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

FORM 10-K

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

For the fiscal year ended December 31 , 2023

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

For the transition period from _____ to _____

Commission File No. 001-41097

CARDIO DIAGNOSTICS HOLDINGS, INC.

(Exact name of registrant as specified in its charter)

Delaware	**87-0925574**
(State or Other Jurisdiction of Incorporation or Organization)	(I.R.S. Employer Identification No.)

311 West Superior Street , Suite 444
Chicago , IL 60654
(Address of principal executive offices and Zip Code)

(302) 281-2147
(Registrant's telephone number, including area code)

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

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock, par value $0.00001	CDIO	The Nasdaq Stock Market LLC
Redeemable warrants, each warrant exercisable for one share of common stock	CDIOW	The Nasdaq Stock Market LLC

Securities registered pursuant to Section 12(g) of the Securities Exchange Act: NONE

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

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

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

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

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

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

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐
Indicate by check mark whether the registrant has filed a report on and attestation to its management's assessment of the effectiveness of its internal control over financial reporting under Section 404(b) of the Sarbanes-Oxley Act (15 U.S.C. 7262(b)) by the registered public accounting firm that prepared or issued its audit report. ☐

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

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

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

As of June 30, 2023, the aggregate market value of shares held by non-affiliates of the registrant (based upon the closing sale prices of such shares on the Nasdaq Capital Market on June 30, 2023) was approximately $ 9.4 million. For purposes of calculating the aggregate market value of shares held by non-affiliates, we have assumed that all outstanding shares are held by non-affiliates, except for shares held by each of our executive officers, directors, and 5% or greater stockholders. In the case of 5% or greater stockholders, we have not deemed such stockholders to be affiliates unless there are facts and circumstances which would indicate that such stockholders exercise any control over our company, or unless they hold 10% or more of our outstanding common stock. These assumptions should not be deemed to constitute an admission that all executive officers, directors, and 5% or greater stockholders are, in fact, affiliates of our company, or that there are not other persons who may be deemed to be affiliates of our company.

As of April 1, 2024, there were 21,591,119 shares of common stock, par value $0.00001 issued and outstanding.

Documents Incorporated by Reference: None.

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INTRODUCTORY NOTE

Unless the context dictates otherwise, references in this Annual Report on Form 10-K to the "Company," "Cardio," "we," "us," "our," and similar words are references to Cardio Diagnostics Holdings, Inc., a Delaware corporation, and its consolidated subsidiary. "Legacy Cardio" refers to Cardio Diagnostics, Inc. prior to the October 2022 Business Combination, which became our wholly-owned subsidiary as a result of that transaction.

Trade names and trademarks of Cardio referred to herein, and their respective logos, are our property. This Annual Report on Form 10-K may contain additional trade names and/or trademarks of other companies, which are the property of their respective owners. We do not intend our use or display of other companies' trade names and/or trademarks, if any, to imply an endorsement or sponsorship of us by such companies, or any relationship with any of these companies.

CAUTIONARY NOTE REGARDING FORWARD LOOKING STATEMENTS

This Annual Report on Form 10-K contains forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, or the "Securities Act," and Section 21E of the Securities Exchange Act of 1934, or the Exchange Act. The statements contained in this report that are not purely historical are forward-looking statements. Our forward-looking statements include, but are not limited to, statements regarding our or our management's expectations, hopes, beliefs, intentions or strategies regarding the future. In addition, any statements that refer to projections, forecasts or other characterizations of future events or circumstances, including any underlying assumptions, are forward-looking statements. The words "anticipates," "believe," "continue," "could," "estimate," "expect," "intends," "may," "might," "plan," "possible," "potential," "predicts," "project," "should," "would" and similar expressions may identify forward-looking statements, but the absence of these words does not mean that a statement is not forward-looking. Forward-looking statements in this Form 10-K may include, for example, statements such as the following:

- the possibility that we may be adversely impacted by economic, business, and/or competitive factors;
- our limited operating history makes it difficult to evaluate our business and prospects;
- the success, cost and timing of our product development and commercialization activities, including the degree to which Epi+Gen CHD™, our initial clinical test, PrecisionCHD™, our second clinical test, or HeartRisk™ , our recently introduced software product, are accepted and adopted by patients, healthcare professionals and other participants in other key channels may not meet our current expectations;
- changes in applicable laws or regulations could negatively impact our current business plans;
- we may be unable to obtain and maintain regulatory clearance or approval for our tests, and any related restrictions and limitations of any cleared or approved product could negatively impact our financial condition;
- the pricing of our products and services and reimbursement for medical tests conducted using our products and services may not be sufficient to achieve our financial goals;
- we may be unable to successfully compete with other companies currently marketing or engaged in the development of products and services that could serve the same or similar functions as our products and services;
- the size and growth potential of the markets for our products and services, and our ability to serve those markets, either alone or in partnership with others may not meet our current expectations;
- we may be unable to maintain our existing or future licenses, or manufacturing, supply and distribution agreements;
- we may be unable to identify, in-license or acquire additional technology needed to develop new products or services;
- our estimates regarding expenses, future revenue, capital requirements and needs for additional financing may not be accurate;
- we may be unable to raise needed financing in the future on acceptable terms, if at all;
- we may be unable to maintain our listing on The Nasdaq Stock Market;
- although highly uncertain, our operational and financial performance could be negatively impacted by the potential short and long-term impact of a re-emergence of COVID-19 variants or any other pandemic, epidemic or infectious disease outbreak, the extent of which will depend on future developments, including the duration and spread of the outbreak, the willingness of doctors and patients to use our tests during such times and the impact on our supply chain and the financial markets, all of which are highly uncertain and cannot be predicted; and
- there are other risks and uncertainties indicated in this Annual Report on Form 10-K, including those under "Risk Factors" herein, and other filings that have been made or will be made with the SEC by us that could materially alter our current expectations.

The forward-looking statements contained in this Form 10-K are based on our current expectations and beliefs concerning future developments and their potential effects on us. There can be no assurance that future developments affecting us will be those that we have anticipated. These forward-looking statements involve a number of risks, uncertainties (some of which are beyond our control) or other assumptions that may cause actual results or performance to be materially different from those expressed or implied by these forward-looking statements. Should one or more of these risks or uncertainties materialize, or should any of our assumptions prove incorrect, actual results may vary in material respects from those projected in these forward-looking statements. We undertake no obligation to update or revise any forward-looking statements, whether as a result of new information, future events or otherwise, except as may be required under applicable securities laws.

Risk Factor Summary

Our business is subject to numerous risks and uncertainties, including those highlighted in the section titled "Risk Factors," which represent challenges that we face in connection with the successful implementation of our strategy and growth of our business. The occurrence of one or more of the events or circumstances described in the section titled "Risk Factors," alone or in combination with other events or circumstances, may have an adverse effect on our business, cash flows, financial condition and results of operations. Such risks include, but are not limited to:

Risks Related to Our Business, Industry and Business Operations

- We have a limited operating history that makes it impossible to reliably predict future growth and operating results.
- We have an unproven business model, have not generated significant revenues and can provide no assurance of generating significant revenues or operating profit.
- The market for epigenetic tests is fairly new and unproven, and it may decline or experience limited growth, which would adversely affect our ability to fully realize the potential of our business plan.
- The estimates of market opportunity and forecasts of market growth included in this Annual Report on Form 10-K may prove to be inaccurate, and even if the market in which we compete achieves the forecasted growth, our business could fail to grow at similar rates, if at all.
- If we are not able to enhance or introduce new products that achieve market acceptance and keep pace with technological developments, our business, results of operations and financial condition could be harmed.
- The success of our business depends on our ability to expand into new vertical markets and attract new customers in a cost-effective manner.
- Our growth strategy may not prove viable and expected growth and value may not be realized.
- Our future growth could be harmed if we lose the services of our key personnel.
- We may face intense competition, which could limit our ability to maintain or expand market share within our industry, and if we do not maintain or expand our market share, our business and operating results will be harmed.
- Our business depends on customers increasing their use of our existing and future products, and we may experience loss of customers or a decline in their use of our solutions.
- We rely on a limited number of suppliers, contract manufacturers, and logistics providers, and our tests are currently performed by a single contract high complexity Clinical Laboratory Improvement Amendments (CLIA) laboratory.
- We may be unable to scale our operations successfully.
- As we grow the size of our organization, we may experience difficulties in managing this growth.
- Our success depends upon our ability to adapt to a changing market and our continued development of additional tests and services.
- Our Board of Directors may change our strategies, policies, and procedures without stockholder approval.
- We may need to seek alternative business opportunities and change the nature of our business.
- We may be subject to general litigation that may materially adversely affect us and our operations.
- Our management expects to continue to devote substantial time to maintaining and improving its internal controls over financial reporting and the requirements of being a public company which may, among other things, strain our resources, divert management's attention and affect our ability to accurately report our financial results and prevent fraud.

Risks Related to Our Intellectual Property

- Certain of our core technology is licensed, and that license may be terminated if we were to breach our obligations under the license.
- Our license agreement with University of Iowa Research Foundation (UIRF) includes a non-exclusive license of "technical information" that potentially could grant unaffiliated third parties access to materials and information considered derivative work made by us, which could be used by such licensees to develop competitive products.

Risks Related to Government Regulation

- We conduct business in a heavily regulated industry, and if we fail to comply with these laws and government regulations, we could incur penalties or be required to make significant changes to our operations or experience adverse publicity, which could have a material adverse effect on our business, financial condition, and results of operations.
- If the U.S. Food and Drug Administration ("FDA") were to begin actively regulating our tests, we could incur substantial costs and delays associated with trying to obtain premarket clearance or approval and incur costs associated with complying with post-market controls.
- If our products do not receive adequate coverage and reimbursement from third-party payors, our ability to expand access to our tests beyond our initial sales channels will be limited and our overall commercial success will be limited.

Risks Related to Our Common Stock

- The price of our Common Stock likely will be volatile like the stocks of other early-stage companies.
- Because a substantial number of our currently outstanding shares of Common Stock are registered for resale, we may have difficulty raising additional capital when and if needed.
- A significant number of shares of our Common Stock are subject to issuance upon exercise of outstanding warrants and options, which upon such exercise may result in dilution to our security holders.
- We have never paid dividends on our Common Stock, and we do not anticipate paying any cash dividends on our Common Stock in the foreseeable future.
- Sales of a substantial number of shares of our Common Stock in the public market by our existing stockholders could cause our stock price to decline.

Part I

Item 1. Business

References in this report to "Cardio," "we," "us" or the "Company" refer to Cardio Diagnostics Holdings, Inc. References to our "management" or our "management team" refer to the officers and directors of Cardio Diagnostics Holdings, Inc.

Our Company

Cardio Diagnostics, Inc. ("Legacy Cardio") was founded in 2017 in Coralville, Iowa by Meeshanthini (Meesha) Dogan, PhD, and Robert (Rob) Philibert, MD PhD. It was formed in January 2017 as an Iowa LLC and was subsequently incorporated as a Delaware C Corp in September 2019.

Cardio was formed to further develop and commercialize a series of products for major types of cardiovascular disease and associated co-morbidities, including coronary heart disease ("CHD"), stroke, heart failure and diabetes, by leveraging our Artificial Intelligence ("AI")-driven Integrated Genetic-Epigenetic Engine™. As a company, we aspire to give every American adult insight into their unique risk for various cardiovascular diseases. Cardio aims to become one of the leading medical technology companies for enabling improved prevention, detection, treatment and management of cardiovascular disease and associated co-morbidities. Cardio is transforming the approach to cardiovascular medicine from reactive to proactive and hopes to accelerate the adoption of Precision Medicine for all. We believe that incorporating our solutions into routine clinical practice in and prevention efforts can help alter the trajectory that nearly one in two Americans is expected to develop some form of cardiovascular disease by 2035.

According to the CDC, epigenetics is the study of how a person's behaviors and environment can cause changes that affect the way a person's genes work. Unlike genetic changes, epigenetic changes are reversible and do not change one's DNA sequence, but they can change how a person's body reads a DNA sequence. We believe that we are the first company to develop and commercialize epigenetics-based clinical tests for cardiovascular disease that have clear value propositions for multiple stakeholders including (i) patients, (ii) clinicians, (iii) hospitals/health systems, (iv) employers and (v) payors.

An estimated 80% of cardiovascular disease ("CVD") is preventable, yet, it is responsible for one in every four deaths and remains the number one killer in the United States

for both men and women. Coronary heart disease is the most common type of CVD and the major cause of heart attacks. The enormous number of unnecessary heart attacks and deaths associated with CHD is attributable to the failure of current primary prevention approaches in clinical practice to effectively detect, reduce and monitor risk for CHD prior to life altering and costly health complications. Several reasons for this failure include (i) the current in-person risk screening approach is incompatible with busy everyday life; (ii) even if the current risk screening tests are taken, they only identify 44% and 32% of men and women at high risk, respectively; and (iii) the lack of patient care plan personalization. We believe that a highly accessible, personalized and precise solution for CHD prevention is not currently available.

Furthermore, with the ongoing COVID-19 pandemic, preventable illnesses such as CHD are expected to spike. Therefore, now more than ever, there is an urgent need for a highly sensitive, scalable, at-home risk screening tool that can help physicians better direct care and allow patients to receive the help they need sooner.

Our first test, Epi+Gen CHD™, which was introduced for market testing in 2021, is a three-year symptomatic CHD risk assessment clinical blood test targeting CHD events, including heart attacks. In March 2023, we announced the launch of our second product, PrecisionCHD™, an integrated epigenetic-genetic clinical blood test for the detection of coronary heart disease. The Epi+Gen CHD™ and PrecisionCHD™ tests are coupled to Actionable Clinical Intelligence (ACI), a platform that offers new epigenetic and genetic insights to clinicians prescribing the to help improve chronic care management. In May 2023, we launched CardioInnovate360™, a research-use-only (RUO) solution to support the discovery, development and validation of novel biopharmaceuticals for the assessment and management of cardiovascular diseases. In February 2024, we announce the launch of HeartRisk™, a cardiovascular risk intelligence platform. The Company earned only $950 and $17,065 in revenue for the years ended December 31, 2022 and 2023, respectively. We are continuing to focus our efforts on establishing relationships with larger organizations and channel partners to increase adoption of our solutions. However, this process can take many months and up to as much as a year or more to finalize, depending on the sales channel. For example, hospitals routinely take a year or longer to make purchasing decisions. While these relationships take considerable time to establish, we believe that our strategy to pursue larger organizations can provide far greater revenue potential for our existing and future products. We have begun to see results from this recent shift in marketing focus: In October 2023, we announced that we have secured an Innovative Technology Contract from Vizient, Inc., the nation's largest provider-driven healthcare performance improvement company, with a customer base encompassing over 60% of hospitals and 97% of academic medical centers in the United States. In November 2023, we announced that Family Medicine Specialists (FMS), a leading Illinois primary care provider with eight locations, is implementing our heart attack risk assessment test, Epi+Gen CHD™, covering at least 1,200 BlueCross BlueShield Medicare, Medicaid, HMO and PPO health plan and other health plan patients with CHD risk factors.

We believe that our Epi+Gen CHD™ and PrecisionCHD™ tests are categorized as laboratory-developed tests, or "LDTs." Under current FDA enforcement discretion policy, an LDT does not require FDA premarket authorization, or other FDA clearance or approval. As such, we believe that the Epi+Gen CHD™ and PrecisionCHD™ tests do not require FDA premarket evaluation of our performance claims or marketing authorization, and such premarket authorization has not been obtained. Although submissions that are pending before the FDA or that have been denied are not publicly available, to the best of our knowledge, no epigenetic-based clinical test for cardiovascular disease has, to date, been cleared or approved by the FDA.

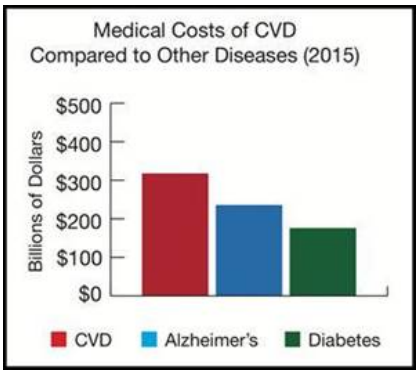
As a company in the early stages of its development, we continuously reevaluate our business, the market in which we operate and potential new opportunities. We may seek other alternatives within the healthcare field in order to grow our business and increase revenues. Such alternatives may include, but not be limited to, combinations or strategic partnerships with other laboratory companies or with medical practices such as hospitalists or behavioral health.

Industry Background

According to the American Heart Association ("AHA"), even though an estimated 80% of cardiovascular disease ("CVD") is preventable, it remains the leading cause of death in the United States and globally. The AHA also reported that over 650,000 deaths in the United States each year are attributable to heart disease, which amounts to one in every four deaths. The Centers for Disease Control and Prevention ("CDC") estimates that in the United States, one person dies every 36 seconds from CVD. Unfortunately, the incidence of CVD is expected to continue to rise with the AHA projecting that by 2035, nearly half of Americans will have some form of CVD.

CVD represents conditions that affect the heart and blood vessels such as coronary heart disease ("CHD"), stroke, and congestive heart failure ("CHF"). CHD is the most common type of heart disease and according to the CDC, was responsible for nearly 370,000 deaths in 2019. The National Center for Health Statistics reported that the prevalence of CHD is approximately 6.7%, and according to the AHA, over 20 million adults aged 20 or older in the United States have CHD. CHD is also the major cause of heart attacks. According to the AHA, every 40 seconds, someone in the United States has a heart attack, with over 800,000 Americans having a heart attack each year. The CDC reported that in 2020, stroke was responsible for one in six CVD-related deaths. The AHA estimates that every year, nearly 800,000 Americans have a stroke which is the leading cause of major long-term disability, with a stroke-related death occurring every 3.5 minutes. According to the AHA, over six million adults have heart failure and nearly 380,000 deaths in 2018 were attributable to heart failure. There are numerous risk factors that could increase an individual's risk for CVD. Several key risk factors include diabetes, high blood cholesterol, and high blood pressure. For example, according to the CDC, over 34 million adults have diabetes and according to Johns Hopkins Medicine, those with diabetes are two to four times more likely to develop CVD. Alongside genetics, age, sex, and ethnicity, lifestyle factors such as smoking, unhealthy diet, physical inactivity, and being overweight can also increase the risk for CVD.

In addition to the enormous morbidity and mortality associated with CVD, the economic burden of CVD is also staggering as depicted in the figure below from the Cardiovascular Disease: A Costly Burden For America, Projections Through 2035 report by the AHA. CVD is the costliest disease in the United States and the economic burden associated with CVD is expected to continue to soar. According to the CDC Foundation, every year, one in six United States healthcare dollars is expended on CVD.



The AHA reports that in 2016, the cost of CVD was $555 billion and is expected to rise to over $1 trillion by 2035. Of the $555 billion, $318 billion was associated with medical costs, and the remaining $237 billion with indirect costs such as lost productivity. By 2035, the medical costs associated with CVD are expected to increase 135% to $749 billion, while the indirect costs are expected to rise by 55% to $368 billion. Currently, among the various types of CVD, the medical costs of CHD are the highest at $89 billion and are expected to rise to $215 billion by 2035 as depicted in the figure below from the Cardiovascular Disease: A Costly Burden For America, Projections Through 2035 report by the AHA.

Projections – CVD Medical Costs Through 2035

	Current	2035
High Blood Pressure	$68 billion	$154 billion
CHD	$89 billion	$215 billion
CHF	$18 billion	$45 billion
Stroke	$37 billion	$94 billion
AFib	$24 billion	$55 billion
Other	$83 billion	$187 billion
TOTAL MEDICAL COSTS	**$318 billion**	**$749 billion**

To address this expected significant rise in human health and economic burdens, the United States healthcare market is seeking more efficient and effective methods to better prevent CVD. This same trend is playing out across developed nations around the globe as the burden of CVD continues to grow due to a rise in major risk factors such as obesity, poor diet and Type 2 diabetes. This is consistent with the cardiovascular diagnostic testing market trends reported by Research and Markets in their Outlook on the Cardiovascular Diagnostic Testing Global Market to 2027 - Increasing Number of Insurance Providers Presents Opportunities press release published on July 4, 2022. They estimate that the Global Cardiovascular Diagnostic Testing Market is estimated to grow from $8.47 billion in 2022 to $12.41 billion by 2027, with a CAGR of 7.94%.

There are several healthcare tailwinds that are driving this expected growth and are expected to support the large-scale adoption of our solutions:

- **The aging population:** According to the Population Reference Bureau, by 2060, the number of Americans aged 65 and over is projected to more than double from 46 million to over 98 million. This demographic shift will result in increased demand for healthcare services in general and for CVD specifically because the risk for CVD increases with age. According to the AHA, the risk for CVD at age 24 is about 20% and more than doubles to 50% by age 45, with 90% of those over the age of 80 having some form of CVD.

- **The rise of chronic diseases:** Chronic diseases such as heart disease, cancer, and diabetes are rising in the United States. The rise of these conditions is further driven by less-than-ideal lifestyle choices such as smoking, an unhealthy diet, and sedentary behavior. As a result, better predictive and diagnostic tools are needed to get ahead of these conditions alongside the need for improved treatment and management of these conditions.
- **The shift to value-based care:** The shift to value-based care drives healthcare providers to focus on quality rather than quantity of care. The shift to value-based care is a crucial driver of growth for Cardio because it incentivizes health care providers to focus on providing quality care rather than simply providing more care. Cardio believes providers can tackle the costliest and deadliest disease category with its solutions while reducing costs.
- **The growth of telemedicine:** Driven largely by the COVID-19 pandemic, telemedicine is a growing trend in healthcare, as it allows patients to receive care from providers remotely. Remote, telemedicine-based preventative programs and tests can serve those who are already undergoing routine screening, but more importantly, expand reach to most Americans who currently are not receiving preventative healthcare, including rural and underserved populations. our evidence-based solutions can be deployed remotely, which is expected to further drive adoption by patients and clinicians.
- **The adoption of Artificial Intelligence (AI):** AI is increasingly incorporated into many aspects of healthcare, including administrative tasks, diagnosis and treatment. AI has the potential to improve the quality of care while reducing costs. Machine learning, which is a type of AI, is instrumental to our cutting-edge solutions, powering their clinical performance and differentiating them from other technologies for CVD.
- **The rise of patient engagement:** Thanks to technology, patients are becoming more engaged in their healthcare. They use online tools to research their conditions and treatments and are more likely to participate in their care. This includes demanding cutting-edge clinical tests that can help them better prevent chronic diseases such as CVD while improving the length and quality of life. As a result, healthcare providers and organizations that offer such services including our solutions are likely to have an edge over those who do not.

Our Strategy

- **Building compelling evidence.** Our AI-driven Integrated Genetic-Epigenetic Engine™ enables rapid design, development, and launch of diagnostic solutions resulting from a decade of research studies. Our solutions that result from this technology, including our Epi+Gen CHD™ test for coronary heart disease risk assessment and PrecisionCHD™ for the early detection of coronary heart disease, were developed through rigorous studies that are peer-reviewed and published and others that are being prepared for peer-reviewed publication in collaboration with leading healthcare and research institutions. In addition to the superior sensitivity of the Epi+Gen CHD™ and PrecisionCHD™ tests, the evidence bases for the Epi+Gen CHD™ test also include an economic case to drive a more holistic and compelling argument for adoption. We plan to continue such studies including similar health economic studies for the PrecisionCHD™ test.

- **Engaging experts and key stakeholders.** At Cardio, we understand that engaging experts and key healthcare stakeholders is critical to realizing our solutions' full potential and ensuring that these solutions reach as many people as possible.

- **Prioritizing and executing strategic acquisitions.** Our expertise at several intersections across biology, machine learning, lab assay development, and cardiovascular disease, provide an array of strategic acquisition opportunities to better serve the cardiovascular disease market by horizontally and vertically integrating the cardiac care continuum.

- **Prioritizing payor coverage.** We believe that to continue to grow the market traction of our solutions, it would require pursuing additional payor coverage. We are engaging the appropriate experts, building necessary evidence, and have a roadmap in place for this. As part of this priority, we are pursuing pilots and strategic collaborations. We expect that it will take six to twelve months to engage additional payors.

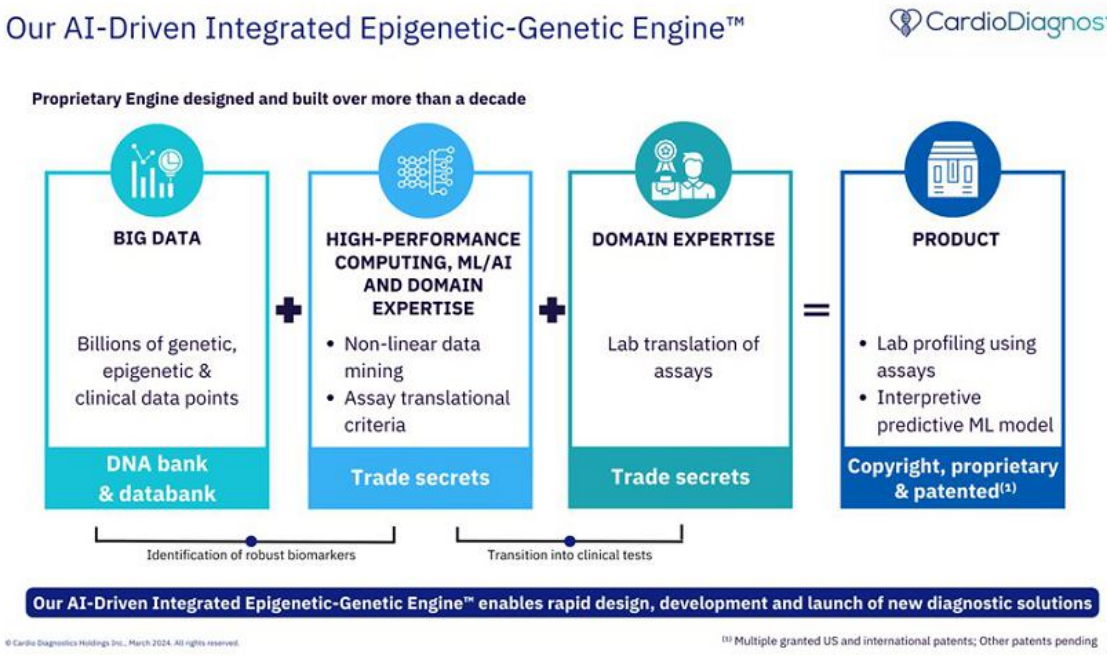
- **Evaluating FDA pathway.** Cardio is evaluating an FDA regulatory pathway to enable broader access to our tests.

- **Targeting multiple revenue channels.** To ensure that our revenue stream is diversified, Cardio has and will continue to target multiple revenue channels for which our solutions have compelling value propositions. This strategy includes, but is not limited to providers, health systems, and employers.

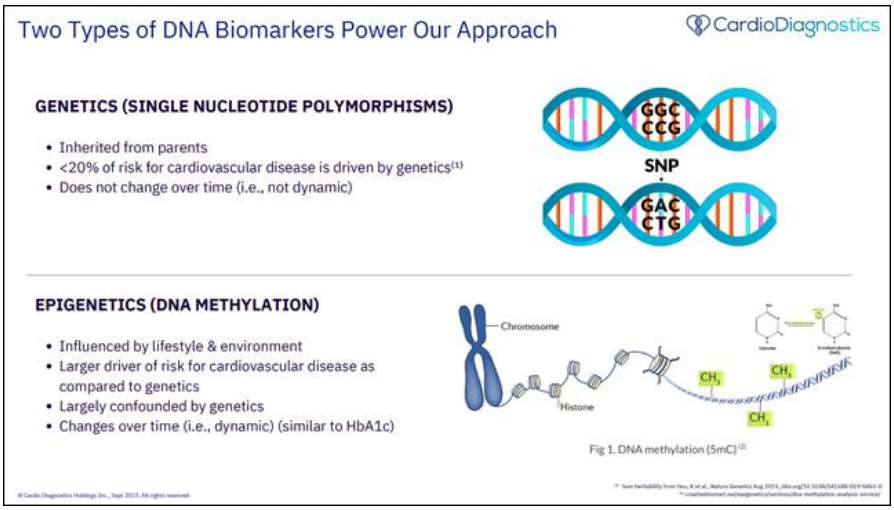
- **Launching synergistic products.** To more fully address cardiovascular health, Cardio is leveraging our AI-driven Integrated Genetic-Epigenetic Engine™ to develop a series of clinical tests for major types of cardiovascular disease and associated co-morbidities, including coronary heart disease, stroke, congestive heart failure and diabetes. We have also started to develop additional synergistic products other than new clinical blood tests. Our first such product, HeartRisk™, is a cardiovascular risk intelligence platform, designed to augment our clinical blood tests.

Our Technology

At the core of Cardio is our proprietary AI-driven Integrated Genetic-Epigenetic Engine™, an engine invented and built by three key employees/officers over the past decade. Our technology enables rapid design, development and launch of new diagnostic solutions through the identification of robust integrated genetic-epigenetic biomarkers and their translation into clinical tests for cardiovascular disease. This engine consists of multiple layers. It begins with genome-wide genetic (single nucleotide polymorphisms or SNPs), genome-wide epigenetic (DNA methylation) and clinical data points. Using high-performance computing, ML/AI techniques and deep domain expertise in medicine, molecular biology and engineering, a panel of SNP-DNA methylation biomarkers and mined, modeled and translated into standalone laboratory assays.



As a result, our products, which are clinical tests, consist of two components. The first is a laboratory component, which involves epigenetic DNA biomarkers. Genetic biomarkers ("SNPs") represent an individual's inherited risk for the disease, have been reported to drive less than 20% of the risk for cardiovascular disease (Hou, K et al, Aug 2019, Nature Genetics) and do not change with intervention (*i.e.*, static). Epigenetic biomarkers (DNA methylation) represent an individual's acquired risk for the disease that is influenced by lifestyle and environment which is a larger driver for cardiovascular risk compared to genetics, is largely confounded by genetics and has been shown to change over time with intervention or changes in one's lifestyle and environment (*i.e.*, dynamic). The second is an analytical component, which involves applying a proprietary interpretive predictive machine learning model to predict risk and provide personalized insights to assist physicians in tailoring a prevention and care plan. The combination of biomarkers and predictive machine learning model is unique to each clinical test we develop.



Our Products and Services

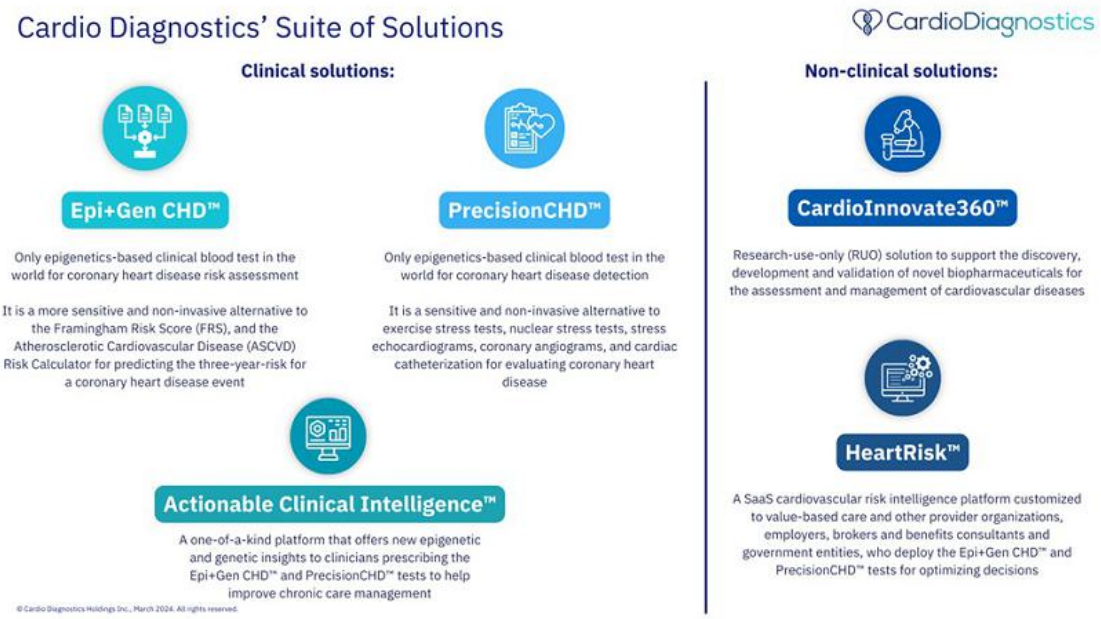
We have and will continue to leverage our AI-driven Integrated Genetic-Epigenetic Engine™ to develop a series of clinical tests for cardiovascular disease. As of March 2024, we have leveraged this Engine to develop two clinical products: Epi+Gen CHD™ and PrecisionCHD™.

We believe that our first product, Epi+Gen CHD™, is the first epigenetics-based clinical blood test capable of assessing near-term (three-year) risk for coronary heart disease ("CHD") and our second product, PrecisionCHD™, is the first epigenetics-based clinical blood test for the detection of CHD.

Both Epi+Gen CHD and PrecisionCHD are accompanied by our provider-only Actionable Clinical Intelligence™ platform, which maps a patient's unique biomarker profile and other information onto modifiable factors such as diabetes, hypertension, hypercholesterolemia and smoking, known to be critical drivers of coronary heart disease.

CardioInnovate360™ is a research use only (RUO) solution we launched to support the discovery, development and validation of novel biopharmaceuticals for the assessment and management of cardiovascular diseases.

Recently, we launched our first software product, HeartRisk™. HeartRisk™ is a cardiovascular risk intelligence platform that combines insights from HIPAA-compliant anonymized and aggregated clinical cardiovascular data obtained through our Epi+Gen CHD™ and PrecisionCHD™ clinical blood tests, with industry and geographic data to enable real-time population-level cardiovascular disease ("CVD") risk insights. These insights are customized for the stakeholder implementing our clinical solutions.



Clinicians' Current Approach to Cardiovascular Disease

Currently, a patient's risk for CVD is generally assessed using two common lipid-based clinical tests known as Framingham Risk Score (FRS) and ASCVD Pooled Cohort Equation (PCE). FRS and PCE are 10-year CVD risk calculators that aggregate common clinical variables such as cholesterol and diabetes, demographics and subjective, self-reported information such as smoking status. For the early detection of CHD, tests that are routinely used in a provider setting include stress echocardiograms. These tests have several limitations and are less effective for several reasons:

- In a peer-reviewed published study by Cardio in collaboration with Intermountain Healthcare (Dogan, Meeshanthini & Knight, Stacey & Dogan, Timur & Knowlton, Kirk & Philibert, Robert. (2021). External validation of integrated genetic-epigenetic biomarkers for predicting incident coronary heart disease. Epigenomics. 13. 10.2217/epi-2021-0123), we found that for three-year coronary heart disease risk assessment, the average sensitivity of FRS and PCE was 44% in men and 32% in women. This means that for every 100 men and 100 women deemed "at-risk" for a coronary heart disease event, the test only correctly identifies 44 men and 32 women. Similar study was performed for PrecisionCHD that demonstrates its high sensitivity and is undergoing the process to be peer-reviewed and published.

- In a peer-reviewed published study by Cardio in collaboration with Intermountain Healthcare and University of Iowa Hospitals and Clinics (Philibert, Robert & Dogan, Timur & Knight, Stacey & Ahmad, Ferhaan & Lau, Stanley & Miles, George & Knowlton, Kirk & Dogan, Meeshanthini. (2023). Validation of integrated genetic-epigenetic test for the assessment of coronary heart disease. Journal of American Heart Association. 12:e030934. DOI: 10.1161/JAHA.123.030934), we found that the overall average area under the curve, sensitivity, and specificity in three independent test cohorts for detecting coronary heart disease were 82%, 79%, and 76%, respectively.

- The fasting requirement for current tests could be cumbersome for patients to comply, and the lack of fasting could affect test results.

- The patient care plan that results from these tests generally lack personalization.

- Lipid-based risk assessment tests depend on self-reported, subjective information such as smoking status from patients, and inaccurate information could affect the accuracy of test results.

- Undergoing these tests requires an in-person clinic visit to collect blood samples and other necessary data points such as blood pressure, which may delay or prevent access to primary prevention, e.g., for those who are unable to make time for the visit, have transportation issues or live in rural areas are likely to delay primary prevention altogether. Similarly, to undergo a stress echocardiogram for instance, an in-person visit is required, and such a visit can take weeks to schedule that could delay care for patients especially if they are experiencing symptoms such as chest pain.

- Risk assessment tests were also developed predominantly using data from men and therefore, may be less effective for women.

Epi+Gen CHD™ is the Only Epigenetics-based Clinical Test for Coronary Heart Disease Risk Assessment

Epi+Gen CHD™ is a scientifically backed clinical blood test that is based on an individual's objective genetic and epigenetic DNA biomarkers for assessing the three-year risk for a coronary heart disease such as a heart attack. In a peer-reviewed study done in collaboration with Intermountain Healthcare (Dogan, Meeshanthini & Knight, Stacey & Dogan, Timur & Knowlton, Kirk & Philibert, Robert. (2021). External validation of integrated genetic-epigenetic biomarkers for predicting incident coronary heart disease. Epigenomics. 13. 10.2217/epi-2021-0123), this test demonstrated a 76% and 78% sensitivity for men and women, respectively, for three-year CHD risk. This means that for every 100 men and 100 women deemed "at-risk" for a coronary heart disease event, the test correctly identifies 76 men and 78 women. In comparison, the average sensitivity of the Framingham Risk Score and the ASCVD Pooled Cohort Equation was found to be 44% and 32% for men and women, respectively. The performance of the test in this study was evaluated across two cohorts that were independent of each other. One cohort was used for the development of this test and the other was used to independently validate the performance of the test, showing Epi+Gen CHD™ to be approximately 1.7 times and 2.4 times more sensitive than the current lipid-based clinical risk estimators in men and women, respectively. In another peer-reviewed study focusing on the cost utility of Epi+Gen CHD™ (Jung, Younsoo & Frisvold, David & Dogan, Timur & Dogan, Meeshanthini & Philibert, Robert. (2021). Cost-utility analysis of an integrated genetic/epigenetic test for assessing risk for coronary heart disease. Epigenomics. 13. 10.2217/epi-2021-0021), this test was associated with up to $42,000 in cost savings per quality adjusted life year and improved survival compared to the ASCVD Pooled Cohort Equation. In another peer-reviewed study, (Philibert, Willem & Andersen, Allan & Hoffman, Eric & Philibert, Robert & Dogan, Meeshanthini. (2021). The reversion of DNA methylation at coronary heart disease risk loci in response to prevention therapy. Processes. 9, 699. https://doi.org/10.3390/pr9040699), DNA methylation of this test was shown to change within 90 days of intervention in the form of smoking cessation, demonstrating that this test could potentially also be leveraged to evaluate the effectiveness of interventions.

The blood-based version of this test was introduced for market testing in 2021 The pricing of the test varies based on factors such as organization type and test volume. The price of the test and revenue streams could change in the future depending on market forces and payor requirements, as well as on the customer and the region in which the test is being sold. We are building additional clinical and health economics evidence to pursue payor coverage. A key first step in expanding critical payor coverage is to have this test be assigned a CPT PLA code, and recently, the American Medical Association awarded the Epi+Gen CHD™ a CPT PLA code, 0439U.

We believe that the Epi+Gen CHD™ test can benefit numerous healthcare stakeholders. For instance, we believe that this test will enable clinicians to identify patients at-risk in the near-term for CHD-related events, including a heart attack and utilize actionable insights from this test to provide more personalized care for their patients to help prevent the event and improve outcomes. These actionable insights are conveyed via our provider-only Actionable Clinical Intelligence™ platform, which maps a patient's unique biomarker profile and other information onto modifiable factors such as diabetes, hypertension, hypercholesterolemia and smoking, known to be critical drivers of coronary heart disease. In addition to clinicians, we believe that this test can enable healthcare organizations and payors to reduce the cost of care, and employers to understand and manage business risks including healthcare costs. Insights for these stakeholders upon leveraging the Epi+Gen CHD™ test are provided via our new software product, HeartRisk™, which is a cardiovascular risk intelligence platform. The pricing for this platform will be customized based on the organization type and size.

PrecisionCHD™ is the Only Epigenetics-based Clinical Test for the Early Detection of Coronary Heart Disease

PrecisionCHD™ is a scientifically backed clinical blood test that is based on an individual's objective genetic and epigenetic DNA biomarkers for the detection of coronary heart disease. In a peer-reviewed published study by Cardio in collaboration with Intermountain Healthcare and University of Iowa Hospitals and Clinics (Philibert, Robert & Dogan, Timur & Knight, Stacey & Ahmad, Ferhaan & Lau, Stanley & Miles, George & Knowlton, Kirk & Dogan, Meeshanthini. (2023). Validation of integrated genetic-epigenetic test for the assessment of coronary heart disease. Journal of American Heart Association. 12:e030934. DOI: 10.1161/JAHA.123.030934), this test demonstrated an overall average area under the curve, sensitivity, and specificity in three independent test cohorts for detecting coronary heart disease of 82%, 79%, and 76%, respectively. The average sensitivity for men and women were 80% and 76%, respectively. This means that for every 100 men and 100 women deemed "to have" coronary heart disease, the test correctly identifies 80 men and 76 women. In comparison, the most commonly used and least invasive test for detecting coronary heart disease, exercise ECG, has a sensitivity of only 58%. The performance of the test in this study was evaluated across three cohorts that were independent of each other. One cohort was used for the development of this test and the other two were used to independently validate the performance of the test, showing PrecisionCHD™ to be approximately 1.4 times and 1.3 times more sensitive than an exercise ECG in men and women, respectively, for detecting coronary heart disease. In another peer-reviewed study, (Broyles, Damon & Philibert, Robert. (2023). Precision epigenetics provides a scalable pathway for improving coronary heart disease care globally. Epigenomics. 10.2217/epi-2023-0233), the global scalability of PrecisionCHD was outlined in comparison to commonly used coronary heart disease tests such as exercise ECG and CCTA. Similar to the Epi+Gen CHD™ test, a peer-reviewed study was conducted to evaluate if the DNA methylation biomarkers of PrecisionCHD could be potentially leveraged to evaluate the effectiveness of interventions. In this peer-reviewed study, (Philibert, Robert & Moody, Joanna & Philibert, Willem & Dogan, Meeshanthini & Hoffman, Eric. (2023). The reversion of epigenetic signature of coronary heart disease in response to smoking cessation. Genes. 14, 1233. https://doi.org/10.3390/genes14061233), DNA methylation of this test was shown to change within 90 days of intervention in the form of smoking cessation.

The blood-based version of this test was introduced for market testing in 2023. The pricing of the test varies based on factors such as organization type and test volume. Recently, the American Medical Association awarded the PrecisionCHD™ a CPT PLA code, 0440U. The price of the test and revenue streams could change in the future depending on market forces and payor requirements, as well as on the customer and the region in which the test is being sold. We are continuing to build clinical and health economics evidence to pursue payor coverage.

We believe that the PrecisionCHD™ test can benefit numerous healthcare stakeholders. For instance, we believe that this test will enable clinicians to identify patients with CHD with a simple blood test and utilize actionable insights from this test to provide more personalized care for their patients to help improve outcomes. These actionable insights are conveyed via our provider-only Actionable Clinical Intelligence™ platform, which maps a patient's unique biomarker profile and other information onto modifiable factors such as diabetes, hypertension, hypercholesterolemia, and smoking, known to be critical drivers of coronary heart disease. In addition to clinicians, we believe that this test can enable healthcare organizations and payors to reduce the cost of care, and employers to understand and manage business risks including healthcare cost. Insights for these stakeholders upon leveraging the PrecisionCHD™ test are provided via our new software product, HeartRisk™, which is a cardiovascular risk intelligence platform. The pricing for this platform will be customized based on the organization type and size. Cardio intends to accelerate the adoption of Epi+Gen CHD™ and PrecisionCHD™ by:

- developing strategic clinical partnerships to reach as many patients as possible;
- leveraging industry organizations to engage and educate providers;
- launching a piloting program to for innovative providers and key strategic partners;
- developing strategic partnerships with other healthcare stakeholders such as payors and employers; and
- developing a customized customer portal to reduce transaction friction.

Cardio foresees potential opportunities to increase the gross margin of the Epi+Gen CHD™ and PrecisionCHD™ by:

- establishing a laboratory to potentially reduce cost associated with processing samples;
- processing patient samples in the laboratory in larger batches;
- shipping sample collection kits in larger batches; and
- increasing the level of automation to reduce manual processing.

FDA Pathway

We have completed a pre-submission with the FDA pertaining to our PrecisionCHD product and have received feedback from the FDA on that submission. We may complete additional pre-submissions to the FDA as we continue to evaluate FDA's feedback and further develop our regulatory strategy. We have engaged outside expertise for this process.

Product Pipeline

In March 2023, we announced the debut of the PrecisionCHD™ test, our second clinical blood test for the detection of CHD. In May 2023, we launched CardioInnovate360™ a research-use-only (RUO) solution to support the discovery, development and validation of novel biopharmaceuticals for the assessment and management of cardiovascular diseases. In February 2024, we announced the launch of HeartRisk™, our first software product that is a cardiovascular risk intelligence platform. We have several other tests in our product pipeline at various stages of development for congestive heart failure, stroke and diabetes. However, as a company in the early stages of its development, we continuously reevaluate our business, the market in which we operate and potential new opportunities. We may modify our product pipeline, seek other alternatives within the healthcare field in order to grow the Company's business and increase revenues. Such alternatives may include, but not be limited to, combinations or strategic partnerships with other laboratory companies or with medical practices such as hospitalists or behavioral health.

Our Market Opportunity

Cardiovascular disease ("CVD") is the leading cause of death in the United States, accounting for one in four deaths. Despite being largely preventable, the American Heart Association projects that by 2035, nearly 45% of Americans will have some form of CVD. One of the key ways to address the prevalence of CVD is to shift the approach for CVD from reactive treatment to proactive prevention and earlier detection. As such, technologies that can more precisely assess the risk for and detect CVD before symptoms emerge or a catastrophic cardiac event occurs becomes even more critical.

According to Research and Markets in their Outlook on the Cardiovascular Diagnostic Testing Global Market to 2027 - Increasing Number of Insurance Providers Presents Opportunities press release published on July 4, 2022, the Global Cardiovascular Diagnostic Testing Market is estimated to grow from $8.47 billion in 2022 to $12.41 billion by 2027, with a CAGR of 7.94%. The increasing prevalence of cardiovascular diseases, technological advancements in cardiovascular disease diagnostics, and the growing number of initiatives to promote cardiovascular disease testing are the major factors driving the growth of this market.

Our principal mission is to enable better detection of the presence and risk of major cardiovascular diseases through a series of clinical tests developed by leveraging our proprietary AI-driven Integrated Genetic-Epigenetic Engine™. Our initial product, Epi+Gen CHD™, is a highly sensitive and accessible clinical test for three-year coronary heart disease ("CHD") risk assessment. Our second product, PrecisionCHD™, is a highly sensitive and accessible clinical test for the detection of CHD.

Using data from the US Census Bureau, Cardio estimates that 146 million adults would potentially benefit from our Epi+Gen CHD™ test, 157 million adults for our PrecisionCHD test, 152 million adults for the congestive heart failure test, 153 million adults for the stroke test and 140 million adults for the diabetes test. The pricing of each of our tests may vary, but the US addressable market equates to $51 billion for Epi+Gen CHD™, assuming a pricing of $350/test, $134 billion for PrecisionCHD™, assuming a price of $850/test, $53 billion for congestive heart failure, assuming a pricing of $350/test, $53 billion for stroke, assuming a pricing of $350/test and $49 billion for diabetes, assuming a pricing of $350/test for a total US addressable market of $340 billion. This total addressable market evaluation also assumes that one patient could be tested with multiple tests, and each test is administered to each patient a single time in a year although some patients may benefit from being re-tested in less than a year.

Go-To-Market Strategy for Epi+Gen CHD™ and PrecisionCHD™

Our current go-to-market ("GTM") strategy is predominantly a product-led innovation growth strategy that emphasizes enterprise-wide adoption across key healthcare sub-verticals with a particular emphasis on deeply centralized key opinion and health trend leaders like innovative providers, health systems, and employers. This strategy is augmented with a bottom-up consumer-led sales focused on directly acquiring and retaining savvy and health-conscious consumers interested in using the latest technologies to address their cardiovascular disease risk concerns.

Healthcare Sub-Vertical Priorities for Epi+Gen CHD™ and PrecisionCHD™

By assessing the risk for CHD early and/or detecting CHD early to potentially avert a heart attack, we believe that the clinical and economic utility of the Epi+Gen CHD™ and PrecisionCHD™ tests will support their commercial adoption. We believe that Epi+Gen CHD™ and PrecisionCHD™ can address a significant addressable market opportunity even before these tests are covered and reimbursed by payors. While we believe that such coverage and reimbursement would be necessary to gain widespread adoption, obtaining such coverage and reimbursement from federal and private payors may take several years, if it is obtained at all. We intend to focus on the following key channels as part of our GTM strategy:

· Innovative Health Systems

As innovative health systems diversify their business models and care delivery pathways, there is a renewed emphasis on using precision medical technologies to better manage expensive and chronic conditions, including CHD. By assessing the risk for CHD before a cardiac event, Epi+Gen CHD™ has the potential to improve population health. We believe that the improved performance of our test compared to other risk calculators, coupled with evidence of cost savings and enhanced survival, will drive the adoption of Epi+Gen CHD™ by health systems to continue improving the health of their patients. Similarly, with PrecisionCHD™, innovative health systems are able to help test their patients detect CHD earlier with a simple blood test, potentially leading to better patient outcomes.

· Physician-Directed Channels, Including Concierge Practices

Early adoption is driven by practices committed to innovation in medicine for patients who are more focused on preventive health and wellness and have the financial means to pay out-of-pocket for concierge subscription services. There is a convergence in innovative providers, health-conscious consumers, and best-in-class tests and technologies in concierge medicine practices to provide on-demand elite personalized and readily accessible healthcare. With an estimated 2,000 to 5,000 concierge practices in the United States, there is robust growth in high-end healthcare services with an equal demand for innovative diagnostic tools. Additionally, concierge practices are not price-sensitive, so reimbursement is not a top priority.

· Employers

Early adoption in the employer space is likely to be driven by self-insured employers and employers looking to provide employee perks relevant to health. Self-insured employers are consistently seeking solutions to help manage their biggest cost centers such as heart disease. In a post-pandemic world, the health and wellbeing of employees are also top-of-mind for many employers to ensure that their employees are healthy and productive. Employers view healthcare investments as another investment in the business. Employers leveraging innovative diagnostic solutions can connect better health for employees to drive overall business objectives and have a competitive advantage in managing business risks while attracting and retaining talent.

· Telemedicine and Marketplaces

Many Americans are concerned about being proactive with their health needs. Understanding their personalized risk with tests at the forefront of medicine is crucial for those with financial resources. According to the U.S. Census Bureau based on the 2020 census, there are nearly 44 million households that earn $100,000 or more annually. We expect high-earning Americans who are proactive about their health to constitute the initial attainable market.

Recent GTM Progress and Announcements

Since our last 10Q filing for the period ending in September 30, 2023, we have announced several key milestones, initiatives and progress. Some of those include:

· Planned launch of a new lab and fulfillment center to expand testing capacity, reduce costs, reduce turnaround time and improved margins.

- Entering into a Supply and Distribution Agreement with one of India's premier organizations, Aimil Ltd, to lay the pre-marketing groundwork via Aimil's extensive healthcare network.

- Receiving an Innovative Technology Contract from Vizient, the largest group purchasing organization with a customer base encompassing 60% of hospitals and 97% of academic medical centers in the US.

- Publication of a key peer-reviewed study on PrecisionCHD development and validation for the detection of coronary heart disease in the Journal of American Heart Association.

- An agreement with Family Medicine Specialists to test at least 1,200 of their BlueCross BlueShield and other health plan patients across four locations.

- Obtained two Current Procedural Terminology (CPT) Proprietary Laboratory Analysis (PLA) codes from the American Medical Association, 0440U for PrecisionCHD and 0439U for Epi+Gen CHD.

- The launch of HeartRisk, a cardiovascular risk intelligence platform, initially for employers to provide insights that combine HIPAA-compliant anonymized and aggregated clinical cardiovascular risk data with industry and geographic data, with the aim of helping employers understand the cardiovascular risks in their workforce compared to population and industry benchmarks.

Sales and Marketing for Epi+Gen CHD™ and PrecisionCHD™ with a Focus on Strategic Channel Partnerships

While our overall sales and marketing initiatives will span the gamut across traditional, print, and digital media, our primary sales and marketing strategy consists of the branding, collaboration, co-marketing, and co-sales opportunities involved in strategic channel partnerships. By prioritizing strategic channel partnerships, we believe we can accelerate our market penetration into the key healthcare sub-verticals we intend to prioritize for our growth. The key to our efforts is a well-defined and executed channel partnership integration strategy that will serve to accelerate the sales cycles for each of our distribution channels. The sales cycles are generally defined as the period in which such distribution channel will turn over its inventory of our tests, which may vary for each distribution channel. Utilizing and developing such strategic channel partnerships, we believe, will generate revenue in a myriad of ways including larger contracts for our Epi+Gen CHD™ and PrecisionCHD™ clinical blood tests, and bundling our solutions alongside other synergistic technologies, services, and products.

Strategic channel partnerships are key for the growth of our solutions. There are several key revenue and strategy benefits to developing a robust channel partnership strategy, including:

- Defensibility and Displacement

Strategic channel partners may have exclusivity agreements for Epi+Gen CHD™ and PrecisionCHD™, which forecloses distribution channels to potential competitors.

- Distribution and Network Effects

Channel partners under consideration for Epi+Gen CHD™ and PrecisionCHD™ strategic partnerships have large, related healthcare and life science networks that we expect to leverage as part of the relationship.

- Bi-Directional Value

The cardiovascular disease space is of paramount concern to stakeholders across the healthcare continuum; the scale of the disease across the population and the associated costs ensures that addressing cardiovascular disease from a payment, cost, patient outcome, and prevention standpoint for stakeholders across the spectrum.

- Pricing Differentiation

The economics of each channel partnership can be crafted independently to offer each strategic partner a per-unit cost relevant to the size of their network.

- Complementary Goods

Bundling Epi+Gen CHD™, PrecisionCHD™, HeartRisk™ and future Cardio solutions alongside complementary clinical, analytics, treatment pathways, and services-consulting for primary prevention optimization with key partners expands the ROI of the investment in our solutions.

Hiring and Talent to Accelerate Growth

Our growth strategy will require investment in internal and external healthcare enterprise sales, marketing and deep customer insights. By combining best-in-class revenue operations technologies with seasoned healthcare sales and marketing experts, we believe we can quickly scale the selling approaches we have outlined and validated to transform the cardiovascular healthcare experience, driving revenue and increased margins. New hires will be targeting the entire continuum of revenue needs, including opportunity identification, campaign design, and execution.

Manufacture/Supply Chain

The content of the sample collections kits for both Epi+Gen CHD™ and PrecisionCHD™ are identical, and we rely on third-party suppliers for kit contents required to collect and transport a blood sample to the lab for processing. These are commonly used supplies that are and can be sourced from multiple distributors. Upon sourcing these contents, they are assembled into lancet-based and vacutainer-based sample collection kits internally and fulfilled. We intend to maintain an inventory of fully assembled kits to meet expected demand for at least six months. However, since there are no particular or unique assembly protocols and assembly is handled internally, the lead time to assemble additional sample collection kits would be minimal after the contents are sourced.

Proprietary genetic and DNA methylation components are sourced from large manufacturers and manufactured under good manufacturing practices ("cGMP"). There are alternative manufacturers for each of these components, and no additional lead time is expected. Laboratory assays that are manufactured under cGMP to specifications are expected to be available to meet anticipated demand for at least six months.

Both the Epi+Gen CHD™ and PrecisionCHD™ clinical blood tests currently are offered as LDTs through an experienced laboratory with the appropriate Clinical Laboratory Improvement Amendments of 1988 ("CLIA") certification and state licensure. However, we are currently setting up an internal operational hub that includes a CLIA laboratory. We anticipate completing this process in 2024. However, we are moving at a measured pace in order to preserve resources, so the timing of completion of the internal CLIA laboratory could be delayed until 2025. We will continue to use the services of our outside laboratory without interruption until our laboratory is operational.

Our Competitive Strengths

Innovation is the key to success. In the rapidly moving cardiac diagnostics space, we believe that we have the team, differentiated technology, and deep technical and business expertise to deliver a market differentiating suite of products for our customers to address unmet clinical needs in the cardiovascular space and help us dominate our market.

The pillar of our strategy has been innovation, from the onset with our technology development and intellectual property that account for future growth, to our commercialization and partnership efforts that bring together key healthcare stakeholders.

We believe that, among other reasons, the future belongs to Cardio based on the following competitive strengths:

· *Technology and products are strongly backed by science.*

Our technology and products stem from over a decade of rigorous scientific research by the Founders in collaboration with other clinical and research experts from leading organizations. Our founders are experts in machine learning approaches in healthcare and in epigenetics with highly-cited peer-reviewed publications. The technology and products are developed and validated with extensive clinical data. The key findings have been published after undergoing stringent independent third-party peer review.

· *Broad intellectual property portfolio protects our current and future products and their applications.*

As of March 2024, our patent portfolio includes five patent families, which encompasses issued patents in the U.S., United Kingdom, France, Germany, Italy, Switzerland, Ireland, Hong Kong, Australia, China, and India, one allowed U.S. patent application, two pending PCT International applications, and more than thirty patent applications pending worldwide, and which are generally directed to methods and compositions for detecting biomarkers associated with cardiovascular disease and diabetes for diagnosis and other applications. In addition, we have extensive trade secrets and know-how, including algorithms and assay designs, that that are critical for the continued development and improvement of our current and future products.

· *Big data and artificial intelligence (machine learning) expertise drive future product development.*

Our expertise in processing billions of clinical genotypic, epigenetic and phenotypic data points to generate critical insights allows us to continue to develop innovative products.

· *Proprietary cutting-edge AI-driven Integrated Genetic-Epigenetic Engine™ accelerates product development.*

We have built a proprietary AI-driven Integrated Genetic-Epigenetic Engine™ that is made up of layers of big data, our algorithms informed by biology and its expert domain knowledge that was designed and built over the past decade and can be leveraged to enable rapid design, development and launch of new diagnostic solutions.

· *Multiple potential product offerings with strong value propositions for key healthcare stakeholders.*

We have built a robust product pipeline for various types of cardiovascular disease and other indications that leverage our AI-driven Integrated Genetic-Epigenetic Engine™ to continue to build market traction. We believe that our current and future products have strong value propositions for various key stakeholders in healthcare. As a result, we believe that our customers will adopt and champion our products.

· *Products that can potentially drive value in multiple ways.*

We believe that our tests are the first epigenetics-based clinical tests for heart disease. Unlike genetic biomarkers that are static, the DNA methylation (epigenetic) biomarkers included in our products are generally dynamic. Therefore, DNA methylation biomarkers can change over time and as a result, in addition to initial assessment, our products could potentially be used to personalize interventions and help monitor the effectiveness of these interventions.

· *Commercial processes that are inherently scalable to meet demand.*

Our commercial pipeline is inherently scalable. Laboratory testing kits consist of easy to synthesize oligonucleotide products, readily available PCR reagents, and can be kitted months in advance. Our lancet and vacutainer-based sampling kits incorporate readily available components that can be sourced from several vendors. Our propriety algorithms can be scaled and automated to process data from thousands of samples. In addition, the laboratory processes can be automated and scaled by adding existing commercial equipment.

· *A leadership team of seasoned healthcare professionals and executives that is led by a visionary founder.*

Cardio is led by a management team with experience in inventing innovative technologies, developing and commercializing clinical products, and building high growth companies.

Competition

Even though we believe that our solutions provide significant advantages over solutions that are currently available from other sources, we expect continued intense competition. This includes companies that are entering the cardiovascular diagnostics market or existing companies that are looking to capitalize on the same or similar opportunities as Cardio is in the clinical and non-clinical spaces. Some of our potential and current competitors have longer operating histories and have, or will have, substantially greater financial, technical, research, and other resources than we do, along with larger, more established marketing, sales, distribution, and service organizations. This could enable our competitors to respond more quickly or efficiently than it can to capture a larger market share, respond to changes in the regulatory landscape or adapt to meet new trends in the market. Having access to more resources, these competitors may undertake more extensive research and development efforts, substantially reduce the time to introducing new technologies, accelerate key hires to drive adoption of their technologies, deploy more far-reaching marketing campaigns and implement a more aggressive pricing policy to build larger customer bases than we have. In some cases, we are competing for the same resources our customers allocate for purchasing cardiovascular diagnostics products or for establishing strategic partnerships. We expect new competitors to emerge and the intensity of competition to increase. There is a likelihood that our competitors may develop solutions that are similar ours and ones that could achieve greater market acceptance than ours. This could attract customers away from our solutions and reduce our market share. To compete effectively, we must scale our organization and infrastructure appropriately and demonstrate that our products have superior value propositions, cost savings, and clinical performance.

The clinical cardiovascular diagnostic space is perhaps the most intensely competitive market space in clinical medicine. Even though we believe our solutions offer significant advantages to existing methods, we expect alternative biomarker assessment approaches to continue to exist and to be developed. With respect to coronary heart disease (CHD) risk assessment and early detection, our competitors use a variety of technologies including genetic, serum lipid-based, imaging, proteomic and "people tracking" approaches.

Genetic testing, both whole genome and more focused panel modalities, is the first type of biomarker assessment and is used by many clinicians to assess lifetime risk for CHD. However, whereas the scientific tenets for this approach are generally accepted, it does not identify when the CHD might develop, and we believe that the relative power of this method for predicting CHD as compared to its Epi+Gen CHD™ test is limited. In addition, whereas the use of this test may divert revenues for testing, this approach is in some respects complementary, and it is conceivable that some clinicians may elect to get both forms of testing to have a more holistic assessment of both short term and lifetime risk.

The best-known biomarker approach is that embodied by the American Heart Association/American College of Cardiology Atherosclerotic Cardiovascular Risk Calculator (referred to ASCVD risk calculator or Pooled Cohort Equation). This method integrates laboratory assessment of serum lipids, blood pressure and self-reported health variables to impute 10-year risk for all forms of atherosclerotic cardiovascular disease (mainly CHD, but also stroke and peripheral artery disease) using a standard algebraic equation. This is the most commonly used method of assessing CHD risk and enjoys general acceptance by the medical community. It is perhaps the most direct competitor for our Epi+Gen CHD™ test. We believe that our test has superior performance, does not require overnight fasting and will eventually provide greater information to the clinician than this current market standard. In addition, we note that our test assesses risk over a three-year window rather than a 10-year window which it believes is a more relevant period of time for patient management.

Imaging modalities are also used to assess risk for and detect CHD. Perhaps the most commonly used imaging method for predicting risk for CHD is Coronary Artery Calcium (“CAC”) screening. In this method, a low intensity computed tomography (“CT”) scan is taken of the heart. Then using this data, the amount of calcium laden plaque is determined and the result used to assess 10-year risk for CHD. Strengths of this approach include the general acceptance of the medical community. Weaknesses include the necessity of exposing patients to x-ray radiation and the inability of the CAC test to monitor patient response. In many ways, this test competes with our test. At the same time, we note that this test is not yet recommended as a primary method for screening low risk individuals, uses a longer risk assessment window, and could actually be used as secondary testing to evaluate patients who are not found to be at low risk using Epi+Gen CHD™ or who are flagged for CHD by the PrecisionCHD™ test.

Proteomic methods, as exemplified by serologic assessments of individual proteins such as c-reactive protein or of entire protein panels, such as that for the HART CADhs or CVE tests from Prevencio are another risk assessment tool. The CADhs test is a good example of a proteomic competitor and predicts the one-year risk for having ≥70% stenosis in a major coronary artery while another Prevencio test HART CVE, predicts one year risk for individuals at risk for developing a major adverse cardiovascular event. Important differences between our tests and their offerings include the window of prediction (three-year vs one-year), the type of technology employed (AI-guided interpretation of genotype and methylation sensitive digital PCR results compared to algorithm interpretation of results from Luminex bead immunoassays). Because we believe that digital PCR based methods are more scalable testing solutions than Luminex bead platforms, we believe that our approach has an advantage.

Finally, researchers have described methods to use wearable devices, such as the Huami wrist device, to predict risk for cardiovascular disease. Although people doubtlessly use these and similar methods derived from wearable devices to assess risk, their exact clinical market penetrance is currently low, and whether they would pose as a direct competitor for our test remains uncertain.

However, the aforementioned is only a snapshot of the current market space in which we currently compete and which we intend to compete in the future. Our intellectual property claims include methods to develop tests for coronary heart disease, as well as incident and prevalent heart failure, stroke and diabetes. The test for prevalent coronary heart disease, whose basis was published in 2018, is well underway, and we expect this test to become a strong competitor for other methods of establishing current CHD, such as exercise treadmill testing, and for monitoring response to CHD treatment.

In summary, the cardiovascular diagnostic space is extremely competitive and fast moving. We believe that the serum lipid, proteomic and to a certain extent, imaging-based modalities are direct competitors for customers and enjoy both large existing market share and substantial financial backing. In addition, it is clear that these existing alternative assessment strategies have significant degrees of scientific literature supporting their use, enjoy backing from key medical constituencies for their use in certain circumstances, and have established strategies for obtaining third party reimbursement. As the population ages, this competition is likely to increase. At the same time, we believe that there are important differences between the current tests offered and our solutions with respect to clinical performance, window of clinical assessment, scalability, capacity for assisting with interventions and response monitoring. However, the other technologies are not static, and we expect refinements and/or combination of existing approaches to vigorously compete for customers in our business space. We will need to scale our efforts, orient our organization appropriately and demonstrate that our products provide better value for our customers.

Intellectual Property

We have made broad pending intellectual property ("IP") claims with respect to the use of epigenetic and gene-methylation interactions for the assessment and monitoring of cardiovascular disease, specifically coronary heart disease, congestive heart failure and stroke, as well as diabetes. Our portfolio falls into five patent families. These patent applications have been filed in the United States and a number of foreign jurisdictions including the European Union, Japan, India, Canada and China. In the U.S., Patent No. 11,414,704, titled Compositions and Methods for Detecting Predisposition to Cardiovascular Disease, was issued in 2022 to the University of Iowa Research Foundation ("UIRF"), the co-inventors of which are Dr. Dogan and Dr. Philibert, our Chief Executive Officer and Chief Medical Officer, respectively. This patent family also includes issued patents in Europe, China, Australia, India, a notice of allowance in the US, and a number of other pending applications. We have a worldwide exclusive license agreement with UIRF. Under UIRF's Inventions Policy, inventors are generally entitled to 25% of income from earnings from their inventions. Consequently, Dr. Dogan and Dr. Philibert will benefit from this policy.

Our issued and pending patents cover general methods as well as key technological steps that enable these core approaches while facilitating the continued patenting of material included in the patent applications. In addition to the technology licensed from UIRF, we have other patent applications pending relating to improvements to our technology, which are potentially valuable and of possible strategic importance to the Company. We expect to continue to file new patent applications to protect additional products and methodologies as they emerge.

The initial work on our AI-driven Integrated Genetic-Epigenetic Engine™ is derived from work done by our founders while at the University of Iowa. Follow-on work on our core technology also is derived from work done by our founders while at the University of Iowa but was furthered by our founders and Cardio's Chief Technology Officer independent of the University of Iowa. The follow-on work is described in our second, third, fourth and fifth families of patent applications.

The initial work is described in the first family of patents and patent applications and is generally directed to a number of single nucleotide polymorphism ("SNP") biomarkers and a number of methylation site biomarkers that are associated with the presence or the early onset of a number of cardiovascular diseases. The first family of patents and patent applications is owned solely by UIRF and is exclusively licensed by Cardio. As of March 2024, this family includes eleven granted patents, one soon-to-be issued patent (received notice of allowance), and seven pending patent applications. Any and all patents issuing in this family will be solely owned by UIRF and, barring any changes to the UIRF exclusive license agreement, will fall under the exclusive license to Cardio.

The first family is generally directed to biomarkers associated with cardiovascular disease. This family includes issued patents in the US, United Kingdom, France, Germany, Italy, Switzerland, Ireland, Hong Kong, Australia, China and India, an allowed application in the U.S., and pending applications in Australia, Canada, China, Europe, Hong Kong, and Japan. The issued claims in the US, Australia, China and India are directed to methods and/or compositions (e.g., kits) for determining the methylation status of at least one CpG dinucleotide and the genotype of at least one single-nucleotide polymorphism (SNP) that use or include at least one primer for detecting the presence or absence of methylation in a particular region of the genome (referred to as cg12586707) and at least one primer for detecting the presence or absence of a SNP in a particular region of the genome (referred to as rs11597065). The issued claims in the EP patent are similarly directed to compositions (e.g., a kit) for determining the methylation status of at least one CpG dinucleotide and a genotype of at least one SNP that includes at least one primer that detects the presence or absence of methylation in a particular region of the genome (referred to as cg26910465) and at least one primer that detects a SNP in a particular region of the genome (referred to as rs10275666) or another SNP in linkage disequilibrium with the first SNP. The allowed claims in the U.S. are directed to methods for determining the methylation status of at least one CpG dinucleotide and the genotype of at least one SNP that includes at least one primer that detects the presence or absence of methylation in a particular region of the genome (referred to as cg11964099) and at least one primer that detects a SNP in a particular region of the genome (referred to as rs9988960). This family of patents is in-licensed under an exclusive license agreement with UIRF, and is expected to expire in 2037, absent any applicable patent term adjustments or extensions.

The second family is generally directed to biomarkers associated with diabetes. This family includes pending applications in the U.S., Australia, United Arab Emirates, Canada, China, Europe, Hong Kong, India, Japan, Saudi Arabia, and Singapore, with claims directed to compositions (e.g., a kit) that include at least one primer for determining the methylation status of at least one CpG dinucleotide from a group of five different methylation sites, or a different CpG dinucleotide in linkage disequilibrium with one of the listed CpG dinucleotides, and at least one primer for determining the genotype of at least one SNP from a group of five different SNPs, or a different SNP in linkage disequilibrium with one of the listed SNPs. The pending applications also include claims to methods of determining the presence of biomarkers associated with diabetes, claims to a computer-readable medium for performing such methods, and claims to a system for determining the methylation status of at least one CpG dinucleotide and the genotype of at least one SNP. This family is co-owned by Cardio Diagnostics and UIRF, and the UIRF-owned portion is in-licensed under the same exclusive license agreement as the first family. Patents issuing from this second family are expected to expire in 2041, absent any applicable patent term adjustments or extensions.

The second family of patent applications is co-owned by UIRF and Cardio, since Cardio expanded on and further refined some of the original research that was done at the University of Iowa. The ownership of any and all patents that ultimately issue in this family will depend on the specific subject matter that is claimed in each issued patent. For example, depending upon the specific biomarkers claimed and when those biomarkers were identified (*e.g.*, during the initial work at the University of Iowa or during the follow-on work at Cardio), ownership could lie solely with UIRF or Cardio, or ownership could be shared between UIRF and Cardio (*e.g.*, if a claimed biomarker was initially identified at the University of Iowa and its significance with respect to diabetes was further refined by Cardio; or if one of the claimed biomarkers was identified at the University of Iowa and another one of the claimed biomarkers was identified at Cardio).

The third family is generally directed to biomarkers associated with predicting a three-year incidence of cardiovascular disease. This family includes applications pending in the U.S., Australia, United Arab Emirates, Canada, China, Europe, Hong Kong, India, Japan, Saudi Arabia, and Singapore, with claims directed to compositions (e.g., a kit) that include at least one primer for determining the methylation status of at least one CpG dinucleotide from a group of three different methylation sites, or a different CpG dinucleotide in linkage disequilibrium with one of the listed CpG dinucleotides, and at least one primer for determining the genotype of at least one SNP from a group of five different SNPs, or a different SNP in linkage disequilibrium with one of the listed SNPs. The pending applications also include claims to methods of determining the presence of biomarkers associated with three-year incidence of cardiovascular disease, claims to a computer-readable medium for performing such methods, and claims to a system for determining the methylation status of at least one CpG dinucleotide and the genotype of a SNP. This family of patents is owned exclusively by Cardio Diagnostics. Patents issuing from this third family are expected to expire in 2041, absent any applicable patent term adjustments or extensions.

The fourth family is generally directed to computer resources (e.g., a dashboard) designed by Cardio Diagnostics for use by their stakeholders (e.g., patients, physicians, researchers, insurance companies, etc.). The computer resources are designed to provide results as well as information and context related to Cardio Diagnostics tests and the specific biomarkers that are used. The pending claims are directed to methods of displaying relevant information including genetic marker test results as well as probability analysis (based on, e.g., the population, age, and/or gender of patients), and hyperlinks to relevant literature. The pending application also includes claims to computer-readable media containing instructions for performing such methods and computer systems for executing such instructions. This family currently includes an International PCT application and is solely owned by Cardio Diagnostics. Patents issuing from this fourth family are expected to expire in 2044, absent any applicable patent term adjustments or extensions.

The fifth family is generally directed to biomarkers associated with detecting cardiovascular disease. The pending claims are directed to compositions (e.g., a kit) that include at least one primer for determining the methylation status of at least one CpG dinucleotide from a group of six different methylation sites, or a different CpG dinucleotide in linkage disequilibrium with one of the listed CpG dinucleotides, and at least one primer for determining the genotype of at least one SNP from a group of ten different SNPs, or a different SNP in linkage disequilibrium with one of the listed SNPs. The pending application also includes claims to methods of determining the presence of biomarkers associated with

detecting cardiovascular disease, claims to a computer-readable medium for performing such methods, and claims to a system for determining the methylation status of at least one CpG dinucleotide and the genotype of a SNP. This family currently includes an International PCT application, a U.S. utility application, and an Indian application . Patents issuing from this fifth family are expected to expire in 2044, absent any applicable patent term adjustments or extensions.

The Exclusive License Agreement entered into with UIRF and those licenses granted under that license agreement terminate on the expiration of the patent rights licensed under the license agreement, unless certain proprietary, non-patented technical information is still being used by Cardio, in which case the license agreement will not terminate until the date of termination of such use. The licenses under the license agreement could terminate prior to the expiration of the licensed patent rights if we materially breach our obligations under the license agreement, including failing to pay the applicable license fees and any interest on such fees, and failing to fully remedy such breach within the period specified in the license agreement, or if we enter liquidation, have a receiver or administrator appointed over any assets related to the license agreement, or if we cease to carry on business, file for bankruptcy or if an involuntary bankruptcy petition is filed against the Cardio

Additionally, we have considerable IP in the form of trade secrets, including bioinformatics and high-performance computing techniques and artificial intelligence and machine learning algorithms used to identify genetic and epigenetic biomarkers for various products and to interpret genetic and epigenetic data from patient samples to generate clinically actionable information, as well as the methods to develop new methylation sensitive assays. We protect our proprietary information, which includes, but is not limited to, trade secrets, know-how, and copyrights. Our future success depends on protecting that knowledge, obtaining trademarks on our products, copyright on key materials, and avoiding infringing on the IP rights of others. Where appropriate, we will assess the operating space and acquire licenses for critical technologies that we do not possess or cannot create. We continue to invest in technological innovation and will seek mutualistic and symbiotic licensing opportunities to promote and maintain our competitive position.

In order to provide our products, we currently use a variety of third party technologies including, for example, genotyping, digital methylation assessment and data processing technologies. The terms of these agreements for the non-exclusive use of these technologies are subject to change without notice and could affect our ability to deliver our solutions. In addition, from time to time, we may face claims from third parties asserting ownership of, or demanding release of, the open-source software or derivative works that we developed using such software (which could include our proprietary source code), or otherwise seeking to enforce the terms of the applicable open-source license. These claims could result in litigation that could be costly to defend, have a negative effect on our operating results and financial condition or require us to devote additional research and development resources to change our existing or future solutions. Responding to any infringement or noncompliance claim by an open-source vendor, regardless of its validity, discovering certain open-source software code in our products, or a finding that we have breached the terms of an open-source software license, could harm our business, results of operations and financial condition. In each case, we would be required to either seek licenses to software or services from other parties and redesign our products to function with such other parties' software or services or develop these components internally, which would result in increased costs and could result in delays to product launches. Furthermore, we might be forced to limit the features available in our current or future solutions.

Government Regulation

The laboratory testing and healthcare industry and the practice of medicine are extensively regulated at both the state and federal levels, and additionally, the practice of medicine is similarly extensively regulated by the various states. our ability to operate profitably will depend in part upon its ability, and that of its vendor partners, to maintain all necessary licenses and to operate in compliance with applicable laws and rules. Those laws and rules continue to evolve, and therefore we devote significant resources to monitoring relevant developments in FDA, CLIA, healthcare and medical practice regulation. Those laws and rules include, but are not limited to, ones that govern the regulation of clinical laboratories in general and the regulation of LDTs in particular. As discussed below, legislation has been introduced in Congress that, if enacted, would substantially alter federal regulation of diagnostic tests, including LDTs. As the applicable laws and rules change, we are likely to make conforming modifications in our business processes from time to time. In many jurisdictions where we operate, neither our current nor our anticipated business model has been the subject of judicial or administrative interpretation. We cannot be assured that a review of our business by courts or regulatory authorities will not result in determinations that could adversely affect our operations or that the laboratory and healthcare regulatory environment will not change in a way that restricts our operations.

State and Federal Regulatory Issues

Clinical Laboratory Improvement Amendments of 1988 and State Regulation

Clinical laboratories are required to hold certain federal and state licenses, certifications and permits to conduct our business. As to federal certifications, in 1988, Congress passed the Clinical Laboratory Improvement Amendments of 1988, or ("CLIA"), establishing more rigorous quality standards for all commercial laboratories that perform testing on human specimens for the purpose of providing information for the diagnosis, prevention, or treatment of disease or the assessment of the health of human beings. CLIA requires such laboratories to be certified by the federal government and mandates compliance with various operational, personnel, facilities administration, validation, quality and proficiency testing requirements intended to ensure the accuracy, reliability and timeliness of patient test results. CLIA certification is also a prerequisite to be eligible to bill state and federal healthcare programs, as well as many commercial third-party payers, for laboratory testing services. The Centers for Medicare & Medicaid Services ("CMS") regulates laboratories that perform testing on individuals in the U.S. through CLIA.

Laboratories must comply with all applicable CLIA requirements. If a clinical laboratory is found not to comply with CLIA standards, the government may impose sanctions, limit or revoke the laboratory's CLIA certificate (and prohibit the owner, operator or laboratory director from owning, operating, or directing a laboratory for two years following license revocation), subject the laboratory to a directed plan of correction, on-site monitoring, civil monetary penalties, civil actions for injunctive relief, criminal penalties, or suspension or exclusion from the Medicare and Medicaid programs.

CLIA provides that a state may adopt laboratory licensure requirements and regulations that are more stringent than those under federal law and requires compliance with such laws and regulations. New York State in particular, has implemented its own more stringent laboratory regulatory requirements. State laws may require the laboratory to obtain state licensure and/or laboratory personnel to meet certain qualifications, specify certain quality control procedures or facility requirements, or prescribe record maintenance requirements. Moreover, several states impose the same or similar state requirements on out-of-state laboratory testing specimens collected or received from, or test results reported back to, residents within that state. Therefore, the laboratory is required to meet certain laboratory licensing requirements for those states in which we offer services or from which we accept specimens and that have adopted regulations beyond CLIA. For more information on state licensing requirements, see "— California Laboratory Licensing," "— New York Laboratory Licensing" and "— Other State Laboratory Licensing Laws."

California Laboratory Licensing

In addition to federal certification requirements for laboratories under CLIA, the laboratory is required under California law to maintain a California state license and comply with California state laboratory laws and regulations. Similar to the federal CLIA regulations, the California state laboratory laws and regulations establish standards for the operation of a clinical laboratory and performance of test services, including the education and experience requirements of the laboratory director and personnel (including requirements for documentation of competency), equipment validations, and quality Management practices. All testing personnel must maintain a California state license or be supervised by licensed personnel.

Clinical laboratories are subject to both routine and complaint-initiated on-site inspections by the state. If a clinical laboratory is found to be out of compliance with California laboratory standards, the California Department of Public Health ("CDPH"), may suspend, restrict or revoke the California state laboratory license to operate the clinical laboratory (and exclude persons or entities from owning, operating, or directing a laboratory for two years following license revocation), assess civil money penalties, and/or impose specific corrective action plans, among other sanctions. Clinical laboratories must also provide notice to CDPH of any changes in the ownership, directorship, name or location of the laboratory. Failure to provide such notification may result in revocation of the state license and sanctions under the CLIA program. Any revocation of a CLIA certificate or exclusion from participation in Medicare or Medicaid programs may result in suspension of the California state laboratory license.

New York Laboratory Licensing

We currently do not conduct tests on specimens originating from New York State. In order to test specimens originating from, and return results to New York State, a clinical laboratory is required to obtain a New York state laboratory permit and comply with New York state laboratory laws and regulations. The New York state laboratory laws, regulations and rules are equal to or more stringent than the CLIA regulations and establish standards for the operation of a clinical laboratory and performance of test services, including education and experience requirements of a laboratory director and personnel, physical requirements of a laboratory facility, equipment validations, and quality Management practices. The laboratory director(s) must maintain a Certificate of Qualification issued by the New York State Department of Health ("NYS DOH") in the permitted test categories.

A clinical laboratory conducting tests on specimens originating in New York is subject to proficiency testing and on-site survey inspections conducted by the Clinical Laboratory Evaluation Program ("CLEP") under the NYS DOH. If a laboratory is found to be out of compliance with New York's CLEP standards, the NYS DOH, may suspend, limit, revoke or annul the New York laboratory permit, censure the holder of the license or assess civil money penalties. Statutory or regulatory noncompliance may result in a laboratory's operator, owners and/or laboratory director being found guilty of a misdemeanor under New York law. Clinical laboratories must also provide notice to CLEP of any

changes in ownership, directorship, name or location of the laboratory. Failure to provide such notification may result in revocation of the state license and sanctions under the CLIA program. Any revocation of a CLIA certificate or exclusion from participation in the Medicare or Medicaid programs may result in suspension of the New York laboratory permit.

The NYS DOH also must approve each LDT before that test is offered to patients located in New York.

Other State Laboratory Licensing Laws

In addition to New York and California, certain other states require licensing of out-of-state laboratories under certain circumstances. We have obtained licenses in the states that we believe require us to do so and believe we are in compliance with applicable state laboratory licensing laws, including Maryland and Pennsylvania. We currently do not conduct tests on specimens originating from Rhode Island.

Potential sanctions for violation of state statutes and regulations can include significant monetary fines, the rejection of license applications, the suspension or loss of various licenses, certificates and authorizations, and in some cases criminal penalties, which could harm our business. CLIA does not preempt state laws that have established laboratory quality standards that are more stringent than federal law.

Laboratory-Developed Tests

The FDA generally considers an LDT to be a test that is designed, manufactured, and used within a single laboratory that is certified under CLIA and meets the regulatory requirements under CLIA to perform high complexity testing. LDTs are performed using a variety of laboratory instruments and reagents and may also incorporate FDA-authorized in vitro diagnostics ("IVDs") that the laboratory modifies in some way and validates for its new use. The FDA has historically taken the position that it has the authority to regulate LDTs as medical devices under the Federal Food, Drug and Cosmetic Act ("FDC Act"), but it has generally exercised enforcement discretion with regard to LDTs. This means that even though the FDA believes it can impose regulatory requirements on LDTs, such as requirements to obtain premarket approval, de novo authorization, or 510(k) clearance of LDTs, it has generally chosen not to enforce those requirements to date. Although FDA has generally exercised enforcement discretion for LDTs, the FDA has stated it retains discretion to require compliance with premarket when FDA deems it appropriate to address significant public health concerns.

In September 2023, the FDA announced a proposed regulation that would, if adopted, alter the FDA's historical exercise of enforcement discretion for LDTs by classifying LDTs as medical devices. The proposed regulation would subject LDTs to a more stringent regulatory framework, including premarket clearance or approval requirements, quality system regulations ("QSR"), and post-market surveillance obligations. Failure to comply with these and other FDA regulations could result in legal actions, including fines and penalties. The FDA has indicated it plans to finalize the proposed rule in the second quarter of 2024, though it is uncertain whether the FDA will finalize the proposed rule on this timeline or at all or whether there would be litigation challenging the final rule.

Legislative proposals addressing the FDA's oversight of LDTs have been previously introduced. In March 2020, the Verifying Accurate, Leading-edge IVCT Development ("VALID") Act of 2020 was introduced in the Senate, which proposed a risk-based regulatory framework for IVDs and LDTs and required premarket approval for some in vitro clinical tests. The VALID Act was reintroduced in June 2021 and again most recently in March 2023; the prospects for enactment are uncertain. In March 2020, the Verified Innovative Testing in American Laboratories ("VITAL") Act of 2020 was introduced in the Senate, which would expressly shift the regulation of LDTs from FDA to CMS. The VITAL Act was reintroduced in May 2021, and has not since been reintroduced. Neither statute has been enacted.

As mentioned above, separately, CMS oversees clinical laboratory operations through the CLIA program.

Regulation by the U.S. Food and Drug Administration

Should the FDA decide to no longer exercise enforcement discretion for LDTs, LDTs would be subject to extensive regulation as medical devices under the FDC Act and its implementing regulations, which govern, among other things, medical device development, testing, labeling, storage, premarket clearance or approval, advertising and promotion and product sales and distribution. To be commercially distributed in the United States, medical devices, including some collection devices used to collect samples for testing, and certain types of software, must receive from the FDA prior to marketing, unless subject to an exemption, clearance of a premarket notification ("510(k) clearance"), premarket approval ("PMA"), or a de novo authorization.

IVDs are a type of medical device that are intended to be used in the diagnosis or detection of diseases or conditions, including a determination of the state of health, through collection, preparation and examination of specimens taken from the human body. IVDs may be used to detect the presence of certain chemicals, genetic information or other biomarkers related to diagnosis or detection of diseases or conditions. IVDs may include tests for disease prediction, prognosis, diagnosis, and screening.

The FDC Act classifies medical devices into one of three categories based on the risks associated with the device and the level of control necessary to provide reasonable assurance of safety and effectiveness. Class I devices are deemed to be low risk and are subject to the fewest regulatory controls. Many Class I devices are exempt from FDA premarket review requirements. Class II devices, including some software products to the extent that they qualify as a device, are deemed to be moderate risk, and generally require clearance through the premarket notification, or 510(k) clearance, process. Class III devices are generally the highest risk devices and are subject to the highest level of regulatory control to provide reasonable assurance of the device's safety and effectiveness. Class III devices typically require a PMA by the FDA before they are marketed. A clinical trial is almost always required to support a PMA application or de novo authorization and is sometimes required for 510(k) clearance. All clinical studies of investigational devices must be conducted in compliance with any applicable FDA and Institutional Review Board requirements. Devices that are exempt from FDA premarket review requirements must nonetheless comply with post-market general controls as described below, unless the FDA has indicated otherwise.

510(k) clearance pathway. To obtain 510(k) clearance, a manufacturer must submit a premarket notification demonstrating to the FDA's satisfaction that the new device is substantially equivalent to a "predicate device." A predicate device is a legally marketed device to which a new device may be compared to for a determination regarding substantial equivalence. A legally marketed device is a device that was previously 510(k)-cleared, a device that received de novo authorization, or a device that was in commercial distribution before May 28, 1976 for which the FDA has not called for submission of a PMA application. The FDA's 510(k) clearance pathway usually takes from three to 12 months from submission, but it can take longer, particularly for a novel type of product.

PMA pathway. The PMA pathway requires proof of the safety and effectiveness of the device to the FDA's satisfaction. The PMA pathway is costly, lengthy, and uncertain. A PMA application must provide extensive preclinical and clinical trial data as well as information about the device and its components regarding, among other things, device design, manufacturing, and labeling. As part of its PMA review process, the FDA will typically inspect the manufacturer's facilities for compliance with QSR requirements, which impose extensive testing, control, documentation, and other quality assurance procedures. The PMA review process typically takes one to three years from submission but can take longer.

De novo pathway. If no predicate device can be identified, a device is automatically classified as Class III, requiring a PMA application. However, the FDA can reclassify, either on its own initiative or in response to a request for de novo classification, for a device for which there was no predicate device if the device is low- or moderate-risk. If the device is reclassified as Class II, the FDA will identify special controls that the manufacturer must implement, which may include labeling, testing, performance standards, or other requirements. Subsequent applicants can rely upon the de novo device as a predicate for a 510(k) clearance, unless the FDA exempts subsequent devices from the need for a 510(k). The de novo route is intended to be less burdensome than the PMA process.

Post-market general controls. After a device, including a device exempt from FDA premarket review, is placed on the market, numerous regulatory requirements apply. These include: the QSR, labeling regulations, registration and listing, the Medical Device Reporting regulation (which requires that manufacturers report to the FDA if their device may have caused or contributed to a death or serious injury or malfunctioned in a way that would likely cause or contribute to a death or serious injury if it were to recur), and the Reports of Corrections and Removals regulation (which requires manufacturers to report to the FDA corrective actions made to, or removal of, products in the field, if such actions were initiated to reduce a risk to health posed by the device or to remedy a violation of the FDC Act which may present a health risk). Depending on the severity of the legal violation that led to correction or removal, the FDA may classify the manufacturer's action as a recall.

The FDA enforces compliance with its requirements through inspection and market surveillance. If the FDA finds a violation, it can institute a wide variety of actions, ranging from an untitled or warning letter sent to manufacturers to enforcement actions such as fines, injunctions, and civil penalties; recall or seizure of products; operating restrictions, partial suspension or total shutdown of production; refusing requests for 510(k) clearance or PMA approval of new products; withdrawal of PMAs already granted; and criminal prosecution.

The FDA has become increasingly active in addressing the regulation of software used to support clinical decision making. In 2016, the 21st Century Cures Act, (the "Cures

Act"), among other things, amended the medical device definition in the FDC Act to exclude certain software from FDA regulation, including clinical decision support ("CDS software") that meets certain criteria. CDS software is exempt from the medical device definition if it: (a) displays, analyzes or prints medical information about a patient or other medical information; (b) is intended for the purpose of supporting or providing recommendations about a patient's care to a health care professional, ("HCP"), user; and (c) provides sufficient information about the basis for the recommendations to the HCP user, so that the HCP user does not rely primarily on any of the recommendations to make a clinical decision about an individual patient; unless (d) the software function acquires, processes, or analyzes a medical image, a signal from an in vitro diagnostic device, or a pattern or signal from a signal acquisition system.

On September 28, 2022, the FDA issued a final guidance document interpreting the Cures Act as it pertains to CDS software. Among other views expressed, the final guidance stated that software functions that assess or interpret the clinical implications or clinical relevance of a signal or pattern, such as those that process or analyze an electrochemical or photometric response generated by an assay and instrument to generate a clinical test result, are not exempt from medical device regulation. The final guidance also stated that software functions that generate risk probabilities or risk scores are not exempt because they provide a specific diagnostic, preventive, or treatment output.

Corporate Practice of Medicine; Fee-Splitting

We contract with various healthcare companies to deliver services to patients. This contractual relationship is subject to various state laws, including those of New York, Texas and California, that prohibit fee-splitting or the practice of medicine by lay entities or persons and are intended to prevent unlicensed persons from interfering with or influencing the physician's professional judgment. In addition, various state laws also generally prohibit the sharing of professional services income with nonprofessional or business interests. Activities other than those directly related to the delivery of healthcare may be considered an element of the practice of medicine in many states. Under the corporate practice of medicine restrictions of certain states, decisions and activities such as scheduling, contracting, setting rates and the hiring and management of non-clinical personnel may implicate the restrictions on the corporate practice of medicine.

State corporate practice of medicine and fee-splitting laws vary from state to state and are not always consistent among states. In addition, these requirements are subject to broad powers of interpretation and enforcement by state regulators. Some of these requirements may apply to any telemedicine company or provider organization we contract with. Failure to comply with regulations could lead to adverse judicial or administrative action against us and/or the providers we work with, civil or criminal penalties, receipt of cease-and-desist orders from state regulators, loss of provider licenses, the need to make changes to the terms of engagement with any telemedicine company or provider organization we contract with that interfere with our business and other materially adverse consequences.

Federal and State Fraud and Abuse Laws

Healthcare Laws Generally

The federal Health Insurance Portability and Accountability Act of 1996, as amended by the Health Information Technology for Economic and Clinical Health Act, or HITECH, and their implementing regulations, which is collectively referred to as HIPAA, established several separate criminal penalties for making false or fraudulent claims to insurance companies and other non-governmental payors of healthcare services. Under HIPAA, these two additional federal crimes are: "Healthcare Fraud" and "False Statements Relating to Healthcare Matters." The Healthcare Fraud statute prohibits knowingly and recklessly executing a scheme or artifice to defraud any healthcare benefit program, including private payors. A violation of this statute is a felony and may result in fines, imprisonment or exclusion from government-sponsored programs. The False Statements Relating to Healthcare Matters statute prohibits knowingly and willfully falsifying, concealing or covering up a material fact by any trick, scheme or device or making any materially false, fictitious or fraudulent statement in connection with the delivery of or payment for healthcare benefits, items or services. A violation of this statute is a felony and may result in fines or imprisonment. This statute could be used by the government to assert criminal liability if a healthcare provider knowingly fails to refund an overpayment. These provisions are intended to punish some of the same conduct in the submission of claims to private payors as the federal False Claims Act covers in connection with governmental health programs.

In addition, the Civil Monetary Penalties Law imposes civil administrative sanctions for, among other violations, inappropriate billing of services to federally funded healthcare programs and employing or contracting with individuals or entities who are excluded from participation in federally funded healthcare programs. Moreover, a person who offers or transfers to a Medicare or Medicaid beneficiary any remuneration, including waivers of co-payments and deductible amounts (or any part thereof), that the person knows or should know is likely to influence the beneficiary's selection of a particular provider, practitioner or supplier of Medicare or Medicaid payable items or services may be liable for civil monetary penalties of up to $10,000 for each wrongful act. Moreover, in certain cases, providers who routinely waive copayments and deductibles for Medicare and Medicaid beneficiaries can also be held liable under the Anti-Kickback Statute and civil False Claims Act, which can impose additional penalties associated with the wrongful act. One of the statutory exceptions to the prohibition is non-routine, unadvertised waivers of copayments or deductible amounts based on individualized determinations of financial need or exhaustion of reasonable collection efforts. The OIG emphasizes, however, that this exception should only be used occasionally to address special financial needs of a particular patient. Although this prohibition applies only to federal healthcare program beneficiaries, the routine waivers of copayments and deductibles offered to patients covered by commercial payers may implicate applicable state laws related to, among other things, unlawful schemes to defraud, excessive fees for services, tortious interference with patient contracts and statutory or common law fraud.

Federal Stark Law

We are subject to the federal self-referral prohibitions, commonly known as the Stark Law. Where applicable, this law prohibits a physician from referring Medicare patients to an entity providing "designated health services" if the physician or a member of such physician's immediate family has a "financial relationship" with the entity, unless an exception applies. The penalties for violating the Stark Law include the denial of payment for services ordered in violation of the statute, mandatory refunds of any sums paid for such services, civil penalties of up to $15,000 for each violation and twice the dollar value of each such service and possible exclusion from future participation in the federally-funded healthcare programs. A person who engages in a scheme to circumvent the Stark Law's prohibitions may be fined up to $100,000 for each applicable arrangement or scheme. The Stark Law is a strict liability statute, which means proof of specific intent to violate the law is not required. In addition, the government and some courts have taken the position that claims presented in violation of the various statutes, including the Stark Law can be considered a violation of the federal False Claims Act (described below) based on the contention that a provider impliedly certifies compliance with all applicable laws, regulations and other rules when submitting claims for reimbursement. A determination of liability under the Stark Law could have a material adverse effect on our business, financial condition and results of operations.

Federal Anti-Kickback Statute

We are also subject to the federal Anti-Kickback Statute. The Anti-Kickback Statute is broadly worded and prohibits the knowing and willful offer, payment, solicitation or receipt of any form of remuneration in return for, or to induce, (i) the referral of a person covered by Medicare, Medicaid or other governmental programs, (ii) the furnishing or arranging for the furnishing of items or services reimbursable under Medicare, Medicaid or other governmental programs or (iii) the purchasing, leasing or ordering or arranging or recommending purchasing, leasing or ordering of any item or service reimbursable under Medicare, Medicaid or other governmental programs. Certain federal courts have held that the Anti-Kickback Statute can be violated if "one purpose" of a payment is to induce referrals. In addition, a person or entity does not need to have actual knowledge of this statute or specific intent to violate it to have committed a violation, making it easier for the government to prove that a defendant had the requisite state of mind or "scienter" required for a violation. Moreover, the government may assert that a claim including items or services resulting from a violation of the Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the False Claims Act, as discussed below. Violations of the Anti-Kickback Statute can result in exclusion from Medicare, Medicaid or other governmental programs as well as civil and criminal penalties, including fines of $50,000 per violation and three times the amount of the unlawful remuneration. Imposition of any of these remedies could have a material adverse effect on our business, financial condition and results of operations. In addition to a few statutory exceptions, the U.S. Department of Health and Human Services Office of Inspector General, or OIG, has published safe-harbor regulations that outline categories of activities that are deemed protected from prosecution under the Anti-Kickback Statute provided all applicable criteria are met. The failure of a financial relationship to meet all of the applicable safe harbor criteria does not necessarily mean that the particular arrangement violates the Anti-Kickback Statute. However, conduct and business arrangements that do not fully satisfy each applicable safe harbor may result in increased scrutiny by government enforcement authorities, such as the OIG.

False Claims Act

Both federal and state government agencies have continued civil and criminal enforcement efforts as part of numerous ongoing investigations of healthcare companies and their executives and managers. Although there are a number of civil and criminal statutes that can be applied to healthcare providers, a significant number of these investigations involve the federal False Claims Act. These investigations can be initiated not only by the government but also by a private party asserting direct knowledge of fraud. These "qui tam" whistleblower lawsuits may be initiated against any person or entity alleging such person or entity has knowingly or recklessly presented, or caused to be presented, a false or fraudulent request for payment from the federal government or has made a false statement or used a false record to get a claim approved. In addition, the improper retention of an overpayment for 60 days or more is also a basis for a False Claim Act action, even if the claim was originally submitted appropriately. Penalties for False Claims Act violations include fines ranging from $5,500 to $11,000 for each false claim, plus up to three times the amount of damages sustained by the federal government. A False Claims Act violation may provide the basis for exclusion from the federally-funded healthcare programs. In addition, some states have adopted similar fraud, whistleblower and false claims provisions.

State Fraud and Abuse Laws

Several states in which we operate have also adopted similar fraud and abuse laws as described above. The scope of these laws and the interpretations of them vary from state to state and are enforced by state courts and regulatory authorities, each with broad discretion. Some state fraud and abuse laws apply to items or services reimbursed by any third-party payor, including commercial insurers, not just those reimbursed by a federally-funded healthcare program. A determination of liability under such state fraud and abuse laws could result in fines and penalties and restrictions on our ability to operate in these jurisdictions.

State and Federal Health Information Privacy and Security Laws

There are numerous U.S. federal and state laws and regulations related to the privacy and security of personally identifiable information, or PII, including health information. In particular, HIPAA establishes privacy and security standards that limit the use and disclosure of protected health information, or PHI, and require the implementation of administrative, physical, and technical safeguards to ensure the confidentiality, integrity and availability of individually identifiable health information in electronic form. Since the effective date of the HIPAA Omnibus Final Rule on September 23, 2013, HIPAA's requirements are also directly applicable to the independent contractors, agents and other "business associates" of covered entities that create, receive, maintain or transmit PHI in connection with providing services to covered entities. Although Cardio is a covered entity under HIPAA, Cardio is also a business associate of other covered entities when Cardio is working on behalf of our affiliated medical groups.

Violations of HIPAA may result in civil and criminal penalties. The civil penalties range from $100 to $50,000 per violation, with a cap of $1.5 million per year for violations of the same standard during the same calendar year. However, a single breach incident can result in violations of multiple standards. Cardio must also comply with HIPAA's breach notification rule. Under the breach notification rule, covered entities must notify affected individuals without unreasonable delay in the case of a breach of unsecured PHI, which may compromise the privacy, security or integrity of the PHI. In addition, notification must be provided to the HHS and the local media in cases where a breach affects more than 500 individuals. Breaches affecting fewer than 500 individuals must be reported to HHS on an annual basis. The regulations also require business associates of covered entities to notify the covered entity of breaches by the business associate.

State attorneys general also have the right to prosecute HIPAA violations committed against residents of their states. While HIPAA does not create a private right of action that would allow individuals to sue in civil court for a HIPAA violation, its standards have been used as the basis for the duty of care in state civil suits, such as those for negligence or recklessness in misusing personal information. In addition, HIPAA mandates that HHS conduct periodic compliance audits of HIPAA covered entities and their business associates for compliance. It also tasks HHS with establishing a methodology whereby harmed individuals who were the victims of breaches of unsecured PHI may receive a percentage of the Civil Monetary Penalty fine paid by the violator. In light of the HIPAA Omnibus Final Rule, recent enforcement activity, and statements from HHS, we expect increased federal and state HIPAA privacy and security enforcement efforts.

HIPAA also required HHS to adopt national standards establishing electronic transaction standards that all healthcare providers must use when submitting or receiving certain healthcare transactions electronically. On January 16, 2009, HHS released the final rule mandating that everyone covered by HIPAA must implement ICD-10 for medical coding on October 1, 2013, which was subsequently extended to October 1, 2015 and is now in effect.

Many states in which we operate and in which patients reside also have laws that protect the privacy and security of sensitive and personal information, including health information. These laws may be similar to or even more protective than HIPAA and other federal privacy laws. For example, the laws of the State of California, in which we operate, are more restrictive than HIPAA. Where state laws are more protective than HIPAA, we must comply with the state laws we are subject to, in addition to HIPAA. In certain cases, it may be necessary to modify our planned operations and procedures to comply with these more stringent state laws. Not only may some of these state laws impose fines and penalties upon violators, but also some, unlike HIPAA, may afford private rights of action to individuals who believe their personal information has been misused. In addition, state laws are changing rapidly, and there is discussion of a new federal privacy law or federal breach notification law, to which we may be subject.

In addition to HIPAA, state health information privacy and state health information privacy laws, we may be subject to other state and federal privacy laws, including laws that prohibit unfair privacy and security practices and deceptive statements about privacy and security and laws that place specific requirements on certain types of activities, such as data security and texting.

In recent years, there have been a number of well-publicized data breaches involving the improper use and disclosure of PII and PHI. Many states have responded to these incidents by enacting laws requiring holders of personal information to maintain safeguards and to take certain actions in response to a data breach, such as providing prompt notification of the breach to affected individuals and state officials. In addition, under HIPAA and pursuant to the related contracts that we enter into with our business associates, we must report breaches of unsecured PHI to our contractual partners following discovery of the breach. Notification must also be made in certain circumstances to affected individuals, federal authorities and others.

State Privacy Laws

Various states have enacted laws governing the privacy of personal information collected and used by businesses online. For example, California adopted the California Consumer Privacy Act of 2018 ("CCPA"), which went into effect on January 1, 2020 and was recently amended by the California Privacy Rights Act of 2020 which significantly modified the CCPA in ways that affect businesses. This law, in part, requires that companies make certain disclosures to consumers via their privacy policies, or otherwise at the time the personal data is collected. We will have to determine what personal data it is collecting from individuals and for what purposes, and to update its privacy policy every 12 months to make the required disclosures, among other things.

Employees and Human Capital Resources

As of April 1, 2024, we had seven full-time employees and two part-time employees. Three of our employees hold Ph.D. or M.D. degrees. We also engage contractors and consultants from time to time. None of our employees are represented by a labor union or covered under a collective bargaining agreement.

Our human capital resources objectives include, identifying, recruiting, retaining, incentivizing and integrating our existing and additional employees into our collaborative culture. Our compensation program is designed to retain, motivate and attract highly qualified executives and talented employees and consultants. We are committed to fostering a culture that supports diversity and an environment of mutual respect, equity and collaboration that helps drive our business and our mission to become one of the leading medical technology companies for enabling improved prevention, detection, treatment and management of cardiovascular disease.

Corporation Information

Our corporate headquarters is located at 311 West Superior Street, Suite 444, Chicago IL 60654. Our telephone number is (855) 226-9991 and our website address is cardiodiagnosticsinc.com. The information contained on, or that can be accessed through, our website is not incorporated by reference in this Annual Report on Form 10-K and does not form a part of this Annual Report on Form 10-K. The reference to our website address does not constitute incorporation by reference of the information contained at or available through our website, and you should not consider it to be a part of this registration statement.

Emerging Growth Status

We are an "emerging growth company," as defined in Section 2(a) of the Securities Act, as modified by the Jumpstart Our Business Startups Act of 2012 (the "JOBS Act"), and we may take advantage of certain exemptions from various reporting requirements that are applicable to other public companies that are not emerging growth companies, including, but not limited to, not being required to comply with the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act of 2002, as amended (the "Sarbanes-Oxley Act"), 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 stockholder approval of any golden parachute payments not previously approved.

Further, Section 102(b)(1) of the JOBS Act exempts emerging growth companies from being required to comply with new or revised financial accounting standards until private companies (that is, those that have not had a registration statement under the Securities Act declared effective or do not have a class of securities registered under the Securities Exchange Act of 1934, as amended the "Exchange Act"), are required to comply with the new or revised financial accounting standards. The JOBS Act provides that a company can elect to opt out of the extended transition period and comply with the requirements that apply to non-emerging growth companies but any such an election to opt out is irrevocable. We have elected not to opt out of such extended transition period which means that when a standard is issued or revised and it has different application dates for public or private companies, we, as an emerging growth company, can adopt the new or revised standard at the time private companies adopt the new or revised standard. This may make comparison of our financial statements with another public company which is neither an emerging growth company nor an emerging growth company which has opted out of using the extended transition period difficult or impossible because of the potential differences in accounting standards used.

We will remain an emerging growth company until the earlier of (1) the last day of the fiscal year (a) following the fifth anniversary of the completion of the IPO, (b) in which we have total annual gross revenue of at least $1.07 billion, or (c) in which we are deemed to be a large accelerated filer, which means the market value of our Common Stock held by non-affiliates equaled or exceeded $700 million as of the prior June 30, and (2) the date on which we have issued more than $1.0 billion in non-convertible debt securities during the prior three-year period.

Additionally, we are a “smaller reporting company” as defined in Item 10(f)(1) of Regulation S-K. Smaller reporting companies may take advantage of certain reduced disclosure obligations, including, among other things, providing only two years of audited financial statements. We will remain a smaller reporting company until the last day of the fiscal year in which (1) the market value of our Common Stock held by non-affiliates equaled or exceeded $250 million as of the end of the prior June 30th, or (2) our annual revenues equaled or exceeded $100 million during such completed fiscal year and the market value of our Common Stock held by non-affiliates equaled or exceeded $700 million as of the prior June 30th.

Available Information

We are required to file Annual Reports on Form 10-K and Quarterly Reports on Form 10-Q with the SEC on a regular basis, and are required to disclose certain material events in a Current Report on Form 8-K. The SEC maintains an Internet website that contains reports, proxy and information statements and other information regarding issuers that file electronically with the SEC. The SEC’s Internet website is located at www.sec.gov. In addition, the Company will provide copies of these documents without charge upon request from us in writing at 311 West Superior Street, Suite 444, Chicago IL 60654.

Item 1A. Risk Factors

RISK FACTORS

Investing in our securities involves risks. You should carefully consider the risks and uncertainties described below and the other information in this Annual Report on Form 10-K before making an investment in our Common Stock. Our business, financial condition, results of operations, or prospects could be materially and adversely affected if any of these risks occurs, and as a result, the market price of our Common Stock could decline and you could lose all or part of your investment. This Annual Report on Form 10-K also contains forward-looking statements that involve risks and uncertainties. See “Cautionary Statement Regarding Forward-Looking Statements.” Our actual results could differ materially and adversely from those anticipated in these forward-looking statements as a result of certain factors, including those set forth below.

Risks Related to Our Limited Operating History and Early Stage of Growth

We are a medical diagnostic testing company with a limited operating history and have not yet generated significant revenue from product sales. We have incurred operating losses since our inception and may never achieve or maintain profitability.

We have generated only nominal revenue in 2022 and 2023, including $950 in revenue generated in 2022 and $17,065 in revenue generated in 2023. Our net losses totaled $4,660,985 and $8,376,834 for the years ended December 31, 2022 and 2023, respectively, and we have an accumulated deficit of $14,368,380 at December 31, 2023. We expect losses to continue as a result of our ongoing activities to increase the adoption of our products, to gain market recognition and acceptance of our products, to expand our marketing channels and otherwise position ourselves to grow our revenue opportunities, all of which will require hiring additional employees as well as other significant expenses. We are unable to predict when we will become profitable, and it is possible that we may never become profitable. We may encounter unforeseen expenses, difficulties, complications, delays, and other unknown factors that may adversely affect our business. The size of our future net losses will depend, in part, on the rate of future growth of our expenses, which we expect to increase substantially as a public company, and on our ability to generate revenue. Even if we achieve profitability in the future, we may not be able to sustain profitability in subsequent periods. If additional capital is not available when required, if at all, or is not available on acceptable terms, we could be forced to modify or abandon our current business plan.

We believe our long-term value as a company will be greater if we focus on growth, which may negatively impact our results of operations in the near term.

We believe our long-term value as a company will be greater if we focus on longer-term growth over short-term results. As a result, our results of operations may be negatively impacted in the near term relative to a strategy focused on maximizing short-term profitability. Significant expenditures on marketing efforts, potential acquisitions and other expansion efforts may not ultimately grow our business or lead to expected long-term results.

Our business and the markets in which we operate are new and rapidly evolving, which makes it difficult to evaluate our future prospects and the risks and challenges we may encounter.

Our business and the markets in which we operate are new and rapidly evolving, which make it difficult to evaluate and assess the success of our business to date, our future prospects and the risks and challenges that we may encounter. These risks and challenges include our ability to:

- attract new customers for our tests through patient awareness, sales and marketing campaigns, as well as through key channel partners;
- gain market acceptance of our current and future tests and services with key constituencies and maintain and expand such relationships;
- comply with existing and new laws and regulations applicable to our business and in our industry;
- anticipate and respond to changes in payor reimbursement rates and the markets in which we operate;
- react to challenges from existing and new competitors;
- maintain and enhance our reputation and brand;
- effectively manage our growth and business operations, including new geographies;
- accurately forecast our revenue and budget for, and manage, our expenses, including capital expenditures; and
- hire and retain talented individuals at all levels of our organization;

If we fail to understand fully or adequately address the challenges that we are currently encountering or that we may encounter in the future, including those challenges described here and elsewhere in this “Risk Factors” section, our business, financial condition and results of operations could be adversely affected. If the risks and uncertainties that we plan for when operating our business are incorrect or change, or if we fail to manage these risks successfully, our results of operations could differ materially from our expectations and our business, financial condition and results of operations could be adversely affected.

Our limited operating history make it difficult to evaluate our future prospects and the risks and challenges we may encounter.

We were established in 2017 and we are continuing to grow our marketing and management capabilities. Consequently, predictions about our future success or viability may not be as accurate as they could be if we had a longer operating history. The evolving nature of the medical diagnostics industry increases these uncertainties. If our growth strategy is not successful, we may not be able to continue to grow our revenue or operations. Our limited operating history, evolving business and growth make it difficult to evaluate our future prospects and the risks and challenges we may encounter.

In addition, as a business with a limited operating history, we may encounter unforeseen expenses, difficulties, complications, delays and other known and unknown challenges. We are not be successful at commercialization, sales and marketing and, as a result, our business may be adversely affected.

Our quarterly results may fluctuate significantly and may not fully reflect the underlying performance of our business.

Our results of operations and key metrics discussed elsewhere in this Annual Report on Form 10-K may vary significantly in the future and period-to-period comparisons of our operating results and key metrics may not provide a full picture of our performance. Accordingly, the results of any one quarter or year should not be relied upon as an indication of future performance. Our quarterly financial results and metrics may fluctuate as a result of a variety of factors, many of which are outside of our control, and as a result they may not fully reflect the underlying performance of our business. These quarterly fluctuations may negatively affect the value of our securities. Factors that may cause these fluctuations include, without limitation:

- the level of demand for our tests and services, which may vary significantly from period to period;
- our ability to attract new customers, whether patients or strategic channel partners or other customers;
- the timing of recognition of revenues;
- the amount and timing of operating expenses;

- general economic, industry and market conditions, both domestically and internationally, including any economic downturns and adverse impacts resulting from the COVID-19 pandemic and/or the military conflict between Russia and Ukraine;
- the timing of our billing and collections;
- adoption rates by participants in our key channels;
- increases or decreases in the number of patients, providers and organizations that use our tests or pricing changes upon any signing and renewals of agreements with healthcare sub-vertical channel partners;
- changes in our pricing policies or those of our competitors;
- the timing and success of new offerings by us or our competitors or any other change in the competitive dynamics of our industry, including consolidation among competitors, practitioners, clinics or outsourcing facilities;

- extraordinary expenses such as litigation or other dispute-related expenses or settlement payments;
- sales tax and other tax determinations by authorities in the jurisdictions in which we conduct business;
- the impact of new accounting pronouncements and the adoption thereof;
- fluctuations in stock-based compensation expenses;
- expenses in connection with mergers, acquisitions or other strategic transactions;
- changes in regulatory and licensing requirements;
- the amount and timing of expenses related to our expansion to markets outside the United States; and
- the timing of expenses related to the development or acquisition of technologies or businesses and potential future charges for impairment of goodwill or intangibles from acquired companies.

Further, in any future period, our revenue growth could slow or our revenues could decline for a number of reasons, including slowing demand for our tests and services, increasing competition, a decrease in the growth of our overall market, or our failure, for any reason, to continue to capitalize on growth opportunities. In addition, our growth rate may slow in the future as our market penetration rates increase. As a result, our revenues, operating results and cash flows may fluctuate significantly on a quarterly basis and revenue growth rates may not be sustainable and may decline in the future, and we may not be able to achieve or sustain profitability in future periods, which could harm our business and cause the market price of our Common Stock to decline.

We expect to need to raise additional capital to fund our existing operations or develop and commercialize new services or expand our operations.

We expect to spend significant amounts to expand our existing operations, including expansion into new geographies, to make additional key hires, to expand our sales channels and constituencies and to develop new tests and services. If we are unable to raise additional capital, we may need to delay the timing of, or scale back, certain aspects of our business plan and operations. The estimate and our expectation regarding the sufficiency of funds to continue our business plan and operations are based on assumptions that may prove to be wrong, and we could use our available capital resources sooner than we currently expect. Until such time, if ever, as we can generate sufficient revenues, we may finance our cash needs through a combination of equity offerings and debt financings or other sources. In addition, we may seek additional capital due to favorable market conditions or strategic considerations, even if we believe that we have sufficient funds for our current or future operating plans.

Our present and future funding requirements will depend on many factors, including:

- our ability to achieve revenue growth;
- our ability to effectively manage our expenses and burn;
- the cost of expanding our operations, including our geographic scope, and our offerings, including our marketing efforts;
- our rate of progress in launching, commercializing and establishing adoption of our tests and services; and
- the effect of competing technological and market developments.

To the extent that we raise additional capital through the sale of equity or convertible debt securities, your ownership interest will be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect your rights as a securityholder. In addition, debt financing and preferred equity financing, if available, may involve agreements that include covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures or declaring dividends. If we raise additional funds through collaborations, strategic alliances or marketing, distribution or licensing arrangements with third parties, we may be required to relinquish valuable rights to our technologies, intellectual property, or future revenue streams or grant licenses on terms that may not be favorable to us. Furthermore, any capital raising efforts may divert our management from their day-to-day activities, which may adversely affect our ability to advance development activities. If we need additional capital and cannot raise it on acceptable terms, or at all, we may not be able to, among other things:

- invest in our business and continue to grow our brand and expand our customer and patient bases;
- hire and retain employees, including scientists and medical professionals, operations personnel, financial and accounting staff, and sales and marketing staff;
- respond to competitive pressures or unanticipated working capital requirements; or
- pursue opportunities for acquisitions of, investments in, or strategic alliances and joint ventures with complementary businesses.

We may invest in or acquire other businesses, and our business may suffer if we are unable to successfully integrate an acquired business into our company or otherwise manage the growth associated with multiple acquisitions.

From time to time, we may acquire, make investments in, or enter into strategic alliances and joint ventures with, complementary businesses. These transactions may involve significant risks and uncertainties, including:

In the case of an acquisition:

- The potential for the acquired business to underperform relative to our expectations and the acquisition price;
- The potential for the acquired business to cause our financial results to differ from expectations in any given period, or over the longer-term;
- Unexpected tax consequences from the acquisition, or the tax treatment of the acquired business's operations going forward, giving rise to incremental tax liabilities that are difficult to predict;
- Difficulty in integrating the acquired business, its operations, and its employees in an efficient and effective manner;
- Any unknown liabilities or internal control deficiencies assumed as part of the acquisition; and
- The potential loss of key employees of the acquired businesses.

In the case of an investment, alliance, joint venture, or other partnership:

- Our ability to cooperate with our co-venturer;
- Our co-venturer having economic, business, or legal interests or goals that are inconsistent with ours; and
- The potential that our co-venturer may be unable to meet is economic or other obligations, which may require us to fulfill those obligations alone or find a suitable replacement.

Any such transaction may involve the risk that our senior management's attention will be excessively diverted from our other operations, the risk that our industry does not evolve as anticipate, and that any intellectual property or personnel skills acquired do not prove to be those needed for our future success, and the risk that our strategic objectives, cost savings or other anticipate benefits are otherwise not achieved.

We may experience difficulties in managing our growth and expanding our operations.

We expect to experience significant growth in the scope of our operations. Our ability to manage our operations and future growth will require us to continue to improve our operational, financial and management controls, compliance programs and reporting systems. We may not be able to implement improvements in an efficient or timely manner and may discover deficiencies in existing controls, programs, systems and procedures, which could have an adverse effect on our business, reputation and financial results. Additionally, rapid growth in our business may place a strain on our human and capital resources.

Risks Related to our Business and Industry

We have an unproven business model with no assurance of significant revenues or operating profit.

Our current business model is unproven and the profit potential, if any, is unknown at this time. We are subject to all of the risks inherent in the creation of a new business. Our ability to achieve profitability is dependent, among other things, on our initial marketing and accompanying product acceptance to generate sufficient operating cash flow to fund current operations and future expansion. There can be no assurance that our results of operations or business strategy will achieve significant revenue or profitability.

The market for epigenetic tests is fairly new and unproven, and it may decline or experience limited growth, which would adversely affect our ability to fully realize the potential of our platform.

Epigenetics is at the heart of our technology, products and services. According to the CDC, epigenetics is the study of how a person's behaviors and environment can cause changes that affect the way a person's genes work. Unlike genetic changes, epigenetic changes are reversible and do not change one's DNA sequence, but they can change how a person's body reads a DNA sequence. The market for epigenetic tests is relatively new and evaluating the size and scope of the market is subject to a number of risks and uncertainties. We believe that our future success will depend in large part on the growth of this market. The utilization of our solution is still relatively new, and customers may not recognize the need for, or benefits of, our tests and services, which may prompt them to cease use of our tests and services or decide to adopt alternative products and services to satisfy their healthcare requirements. In order to expand our business and extend our market position, we intend to focus our marketing and sales efforts on educating customers about the benefits and technological capabilities of our tests and services and the application of our tests and services to specific needs of customers in different market verticals. Our ability to access and expand the market that our tests and services are designed to address depends upon a number of factors, including the cost, performance and perceived value of the tests and services. Market opportunity estimates are subject to significant uncertainty and are based on assumptions and estimates. Assessing the market for our solutions in each of the vertical markets we are competing in, or planning to compete in, is particularly difficult due to a number of factors, including limited available information and rapid evolution of the market. The market for our tests and services may fail to grow significantly or be unable to meet the level of growth we expect. As a result, we may experience lower-than-expected demand for our products and services due to lack of customer acceptance, technological challenges, competing products and services, decreases in expenditures by current and prospective customers, weakening economic conditions and other causes. If our market share does not experience significant growth, or if demand for our solution does not increase, then our business, results of operations and financial condition will be adversely affected.

The estimates of market opportunity and forecasts of market growth included in this Annual Report on Form 10-K may prove to be inaccurate, and even if the market in which we compete achieves the forecasted growth, our business could fail to grow at similar rates, if at all.

Market opportunity estimates and growth forecasts are subject to significant uncertainty and are based on assumptions and estimates that may not prove to be accurate. The estimates and forecasts in this Annual Report on Form 10-K relating to the size and expected growth of the cardiovascular diagnostics market may prove to be inaccurate. Even if the market in which we compete meets our size estimates and forecasted growth, our business could fail to grow at similar rates, if at all.

If we are not able to enhance or introduce new products that achieve market acceptance and keep pace with technological developments, our business, results of operations and financial condition could be harmed.

Our ability to attract new customers and increase revenue from existing customers depends in part on our ability to enhance and improve our solutions, increase adoption and usage of our products and introduce new products and features. The success of any enhancements or new products depends on several factors, including timely completion, adequate quality testing, actual performance quality, market-accepted pricing levels and overall market acceptance and demand. Enhancements and new products that we develop may not be introduced in a timely or cost-effective manner, may contain defects, may have interoperability difficulties with our solutions, or may not achieve the market acceptance necessary to generate significant or any revenue. If we are unable to successfully enhance our existing solutions and capabilities to meet evolving customer requirements, increase adoption and usage of our solutions, develop new products, or if our efforts to increase the usage of our products are more expensive than we expect, then our business, results of operations and financial condition could be harmed.

The success of our business depends on our ability to expand into new vertical markets and attract new customers in a cost-effective manner.

In order to grow our business, we plan to drive greater awareness and adoption of our tests and services from customers across new vertical markets. We intend to increase our investment in sales and marketing, as well as in technological development, to meet evolving customer needs in these and other markets. There is no guarantee, however, that we will be successful in gaining new customers from existing and new markets. We have limited experience in marketing and selling our products and services generally, and in particular in new markets, which may present unique and unexpected challenges and difficulties. Furthermore, we may incur additional costs to modify our current solutions to conform to the customer's requirements, and we may not be able to generate sufficient revenue to offset these costs. We may also be required to comply with certain regulations required by government customers, which will require us to incur costs, devote management time and modify our current solutions and operations. If we are unable to comply with those regulations effectively and in a cost-effective manner, our financial results could be adversely affected.

If the costs of the new marketing channels we use or plan to pursue increase dramatically, then we may choose to use alternative and less expensive channels, which may

not be as effective as the channels we currently use or have plans to use. As we add to or change the mix of our marketing strategies, we may need to expand into more expensive channels than those we are currently in, which could adversely affect our business, results of operations and financial condition. In addition, we have limited experience marketing our products and services and we may not be successful in selecting the marketing channels that will provide us with exposure to customers in a cost-effective manner. As part of our strategy to penetrate the new vertical markets, we expect to incur marketing expenses before we are able to recognize any revenue in such markets, and these expenses may not result in increased revenue or brand awareness. We expect to make significant expenditures and investments in new marketing activities, and these investments may not lead to the cost-effective acquisition of additional customers. If we are unable to maintain effective sales and marketing programs, then our ability to attract new customers or enter into new vertical markets could be adversely affected.

Consolidation in the health care industry could have a material adverse effect on our business, financial condition and results of operations.

Many health care industry participants and payers are consolidating to create larger and more integrated health care delivery systems with greater market power. We expect regulatory and economic conditions to result in additional consolidation in the health care industry in the future. As consolidation accelerates, the economies of scale of our customers' organizations may grow. If a customer experiences sizable growth following consolidation, that customer may determine that it no longer needs to rely on us and may reduce its demand for our products and services. In addition, as health care providers consolidate to create larger and more integrated health care delivery systems with greater market power, these providers may try to use their market power to negotiate price reductions for our products and services. Finally, consolidation may also result in the acquisition or future development by our customers of products and services that compete with our products and services. Any of these potential results of consolidation could have a material adverse effect on our business, financial condition and results of operations.

If we are not able to compete effectively, our business and operating results will be harmed.

The market for our tests and services is increasingly competitive, rapidly evolving and fragmented, and is subject to changing technology and shifting customer needs. Although we believe that the solutions that we offer are unique, many companies develop and market products and services that compete to varying extents with our offerings, and we expect competition in our market to continue to intensify. Moreover, industry consolidation may increase competition.

While the clinical epigenetics market is still fairly new, we face competition from various sources, including large, well-capitalized technology companies such as Cleerly and Prevencio. These competitors may have better brand name recognition, greater financial and engineering resources and larger sales teams than we have. As a result, our competitors may be able to develop and introduce competing solutions and technologies that may have greater capabilities than our solutions or that are able to achieve greater customer acceptance, and they may be able to respond more quickly and effectively than we can to new or changing opportunities, technologies, standards or customer requirements. In addition, we may also compete with smaller companies, who may develop their own platforms that perform similar services as our platform. We expect that competition will increase and intensify as we continue to expand our serviceable markets and improve our tests and services. If we are unable to provide our tests and services on terms attractive to the customer, the prospective customer may be unwilling to utilize our solutions. If our competitors' products, services or technologies become more accepted than our solutions, if they are successful in bringing their products or services to market earlier than we do, or if their products or services are more technologically capable than ours, then our revenue could be adversely affected. In addition, increased competition may result in pricing pressures and require us to incur additional sales and marketing expenses, which could negatively impact our sales, profitability and market share.

Our business depends on customers increasing their use of our solutions, and we may experience loss of customers or decline in their use of our solutions.

Our ability to grow and generate revenue depends, in part, on our ability to maintain and grow our relationships with existing customers and convince them to increase their usage of our tests and services. If our customers do not increase their use of our tests and services, then our revenue may not grow, and our results of operations may be harmed. It is difficult to accurately predict customers' usage levels and the loss of customers or reductions in their usage levels may have a negative impact on our business, results of operations and financial condition. If a significant number of customers cease using, or reduce their usage of our tests and services, then we may be required to expend significantly more on sales and marketing than we currently plan to expend in order to maintain or increase revenue from customers. These additional expenditures could adversely affect our business, results of operations and financial condition.

Our technologies and products leverage and incorporate AI *and machine learning, and their development, maintenance, and operational success are subject to various risks and uncertainties, some of which are beyond our control and may adversely affect our business, results of operations and financial condition, and may also result in reputational harm and liability.*

One of the key components of our technology and solutions is the use of machine learning/artificial intelligence ("ML/AI"). While we have made, and expect to continue to make, investments in the continued development of AI capabilities, adoption of fast changing AI technology presents risks, challenges and potential unintended consequences. Also, the markets for our solutions and services are rapidly evolving and are highly competitive, and many of our competitors are also seeking to incorporate AI into their products. Competing firms may be able to develop and embed AI in their products more quickly than we can. If our competitors are better able to incorporate AI in their products and we are unable to compete effectively with them, our business, results of operations and financial condition could be adversely affected.

Our ML/AI powering our technology and products, there are known risks of with the use of ML/AI including accuracy, bias, toxicity, privacy, security and data provenance. Developing, testing and deploying ML/AI systems may also increase the cost of our offerings. Our failure to adequately address potential risks relating to the use of ML/AI in our technology and solutions could result in litigation regarding, among other things, intellectual property, privacy and other claims that could result in liability for our company. It may also result in new or increased governmental or regulatory scrutiny, which could result in regulatory action, legal liabilities, regulatory penalties, and damage to our reputation, potentially harming our business and financial condition. The use of our AI capabilities could raise ethical or social concerns and our failure to adequately address these concerns or the failure of our competitors, clients or other end users to do so could negatively impact our brand and reputation.

Our success in ML/AI technologies depends significantly on the continued service of our key technical personnel especially our Chief Technology Officer and our Chief Executive Officer, and our ability to attract and retain skilled professionals in a competitive market. The loss of key personnel or the inability to hire and retain the necessary talent could adversely affect our technological competitiveness and operational capabilities.

Interruptions or performance problems associated with our technology and infrastructure may adversely affect our business and operating results.

Our continued growth depends in part on the ability of customers to access its tests and services at any time and within an acceptable amount of time. We may in the future experience disruptions, outages and other performance problems due to a variety of factors, including challenges with suppliers, infrastructure changes, introductions of new applications and functionality, software errors and defects, capacity constraints due to an increasing number of customers or security related incidents. In addition, from time-to-time, we or our vendors may experience limited periods of equipment downtime, server downtime due to server failure or other technical difficulties (as well as maintenance requirements). It may become increasingly difficult to maintain and improve our performance, especially during high volume times and as our solution becomes more complex and our customer demand and traffic increases. If our solution is unavailable or if our customers are unable to access our solutions within a reasonable amount of time or at all, our business would be adversely affected, and its brand could be harmed. In the event of any of the factors described above, or certain other failures of our infrastructure, customer or patient data may be permanently lost. To the extent that we do not effectively address capacity constraints, upgrade our systems, as needed, and continually develop our technology and network architecture to accommodate actual and anticipated changes in technology, customers may cease to use our solutions and our business and operating results may be adversely affected.

We rely on a limited number of suppliers, contract manufacturers, and logistics providers, and our test is performed by a single contract high complexity Clinical Laboratory Improvement Amendments (CLIA) laboratory.

For our Epi+Gen CHD™ and PrecisionCHD™ tests, we and our vendors rely on a limited number of suppliers for laboratory reagents and sampling kit supplies, contract manufacturers, and logistics providers. For example, certain proprietary reagents are manufactured under Good Manufacturing Practice (GMP) by a single contract manufacturer located in Michigan; the blood collection tubes included in the sample collection kits are manufactured by a single manufacturer; and the tests are performed in one high complexity CLIA laboratory located in Missouri. The reliance on a limited number of suppliers and a sole contract manufacturer and laboratory present various risks. These include the risk that in the event of an interruption from any part of our supply chain for any reason, such as a natural catastrophe, labor dispute, or system interruption. We may not be able to develop an alternate source without incurring material additional costs and substantial delays. For example, during 2021, the Coronavirus pandemic impacted the ability to conduct in-person training of personnel at the laboratory, which delayed the launch of Epi+Gen CHD™ by approximately two and a half months. As a public company, the delay of a product launch by a nearly a fiscal quarter could cause our reported results of operations to fail to meet market expectations, which, in turn, and could negatively impact our stock price.

The security of our solutions, networks or computer systems may be breached, and any unauthorized access to our customer data will have an adverse effect on our business and

reputation.

The use of our solutions involves the storage, transmission and processing of our customers' private data, and this data may contain confidential and proprietary information of our customers or their customers, patients, employees, business partners or other persons ("customer personnel") or other personal or identifying information regarding our customers and customer personnel. Individuals or entities may attempt to penetrate our network or platform security, or that of our third-party hosting and storage providers, and could gain access to our customer and customer personnel private data, which could result in the destruction, disclosure or misappropriation of proprietary or confidential information of our customers and customer personnel. If any of our customers' or customer personnel's private data is leaked, obtained by others or destroyed without authorization, it could harm our reputation, we could be exposed to civil and criminal liability, and we may lose our ability to access private data, which will adversely affect the quality and performance of our solutions.

In addition, our platform and services may be subject to computer malware, viruses and computer hacking, fraudulent use attempts and phishing attacks, all of which have become more prevalent in our industry. Though it is difficult to determine what, if any, harm may directly result from any specific interruption or attack, they may include the theft or destruction of data owned by us or our customers or customer personnel, and/or damage to our platform. Any failure to maintain the performance, reliability, security and availability of our products and technical infrastructure to the satisfaction of our customers may harm our reputation and our ability to retain existing customers and attract new customers.

While we have implemented and is continuing to implement procedures and safeguards that are designed to prevent security breaches and cyber attacks, they may not be able to protect against all attempts to breach our systems, and we may not become aware in a timely manner of any such security breach. Unauthorized access to or security breaches of our platform, network or computer systems, or those of our technology service providers, could result in the loss of business, reputational damage, regulatory investigations and orders, litigation, indemnity obligations, damages for contract breach, civil and criminal penalties for violation of applicable laws, regulations or contractual obligations, and significant costs, fees and other monetary payments for remediation. If customers believe that our platform does not provide adequate security for the storage of sensitive information or its transmission over the Internet, our business will be harmed. Customers' concerns about security or privacy may deter them from using our solutions for activities that involve personal or other sensitive information.

We maintain cybersecurity coverage; however, this coverage may not continue to be available on acceptable terms, may not be available in sufficient amounts to cover one or more large claims against us, and may include larger self-insured retentions or certain exclusions. In addition, the insurer might disclaim coverage as to any future claim. A successful claim not fully covered by our insurance could have a material adverse impact on our liquidity, financial condition, and results of operations.

Any failure to offer high-quality customer support may adversely affect our relationships with our customers.

Our ability to retain existing customers and attract new customers depends in part on our ability to maintain a consistently high level of customer service and technical support. Our current and future customers depend on our customer support team to assist them in utilizing our tests and services effectively and to help them to resolve issues quickly and to provide ongoing support. If we are unable to hire and train sufficient support resources or are otherwise unsuccessful in assisting our customers effectively, it could adversely affect our ability to retain existing customers and could prevent prospective customers from adopting our solutions. We may be unable to respond quickly enough to accommodate short-term increases in demand for customer support. We also may be unable to modify the nature, scope and delivery of our customer support to compete with changes in the support services provided by our competitors. Increased demand for customer support, without corresponding revenue, could increase our costs and adversely affect our business, results of operations and financial condition. Our sales are and will be highly dependent on our business reputation and on positive recommendations from customers. Any failure to maintain high-quality customer support, or a market perception that we do not maintain high-quality customer support, could adversely affect our reputation, business, results of operations and financial condition.

The information that we provide to our customers could be inaccurate or incomplete, which could harm our business reputation, financial condition, and results of operations.

We aggregate, process, and analyze customers'/patients' healthcare-related data and information for use by our customers. Because data in the healthcare industry is fragmented in origin, inconsistent in format, and often incomplete, the overall quality of data received or accessed in the healthcare industry is often poor, the degree or amount of data which is knowingly or unknowingly absent or omitted can be material. If the test results that we provide to our customers are based on incorrect or incomplete data or if we make mistakes in the capture, input, or analysis of these data, our reputation may suffer, and our ability to attract and retain customers may be materially harmed.

In addition, in the future, we may assist our customers with the management and submission of data to governmental entities, including CMS. These processes and submissions are governed by complex data processing and validation policies and regulations. If we fail to abide by such policies or submits incorrect or incomplete data, we may be exposed to liability to a client, court, or government agency that concludes that its storage, handling, submission, delivery, or display of health information or other data was wrongful or erroneous.

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

Proprietary software, product and application development is time-consuming, expensive, and complex, and may involve unforeseen difficulties. We may encounter technical obstacles, and it is possible that we discover additional problems that prevent our proprietary solutions from operating properly. If our solutions and services do not function reliably or fail to achieve customer expectations in terms of performance, customers could assert liability claims against us and attempt to cancel their contracts with us. Moreover, material performance problems, defects, or errors in our existing or new solutions may arise in the future and may result from, among other things, the lack of interoperability of our applications with systems and data that we did not develop and the function of which is outside of our control or undetected in our testing. Defects or errors in our solutions might discourage existing or potential customers from purchasing products and services from us. Correction of defects or errors could prove to be time consuming, costly, impossible, or impracticable. The existence of errors or defects in our solutions and the correction of such errors could divert our resources from other matters relating to its business, damage our reputation, increase our costs, and have a material adverse effect on our business, financial condition, and results of operations.

If we do not keep pace with technological changes, our solutions may become less competitive, and our business may suffer.

The clinical epigenetic testing, artificial intelligence/machine learning-based solutions and the cardiovascular diagnostics markets are undergoing rapid technological change, frequent product and service innovation and evolving industry standards. If we are unable to provide enhancements and new features for our existing tests and services or additional tests and services that achieve market acceptance or that keep pace with these technological developments, our business could be adversely affected. The success of enhancements, new tests and services depends on several factors, including the timely completion, introduction and market acceptance of the innovations. Failure in this regard may significantly impair our revenue growth. In addition, because our solutions are designed to operate on existing cloud software and technologies, we will need to continuously modify and enhance our solutions to keep pace with changes in internet-related hardware, software, communication, browser and database technologies, alongside changes in laboratory technologies. We may not be successful in either developing these modifications and enhancements or in bringing them to market in a timely fashion. Furthermore, uncertainties about the timing and nature of new diagnostic tests, network platforms or technologies, including laboratory technologies, or modifications to existing tests, platforms or technologies, could increase our research and development expenses. Any failure of our solutions to keep pace with technological changes or operate effectively with future network platforms and technologies, including laboratory technologies, could reduce the demand for our solutions, result in customer dissatisfaction and adversely affect our business.

Our growth strategy may not prove viable and expected growth and value may not be realized.

While our overall sales and marketing initiatives will span the gamut across traditional, print and digital mediums, our primary sales and marketing strategy consists of the branding, collaboration, co-marketing, and co-sales opportunities involved in strategic channel partnerships. By prioritizing strategic channel partnerships, we believe we can accelerate our market penetration into the key healthcare sub-verticals we intend to prioritize for our growth. The key to our efforts is a well-defined and executed channel partnership integration strategy that we believe will serve to accelerate the sales cycle. Although there is no assurance, we believe such strategic channel partnerships will generate revenue in a myriad of ways, including larger contracts for our Epi+Gen CHD™ and PrecisionCHD™ tests, our HeartRisk platform, and bundling our solutions alongside other synergistic technologies, services, and products. There can be no assurance that we will be successful in acquiring customers through these and other strategies.

Market and economic conditions may negatively impact our business, financial condition and stock price.

Concerns over inflation, energy costs, geopolitical issues, including the ongoing conflict between Russian and Ukraine, unstable global credit markets and financial conditions, and volatile oil prices could lead to periods of significant economic instability, diminished liquidity and credit availability, declines in consumer confidence and discretionary spending, diminished expectations for the global economy and expectations of slower global economic growth going forward. For example, in March 2022, the U.S. Consumer Price Index ("CPI"), which measures a wide-ranging basket of goods and services, rose 8.5% from the same month a year ago, which represents the largest CPI increase since December of 1981. Our general business strategy may be adversely affected by any such inflationary fluctuations, economic downturns, volatile business environments and continued unstable or unpredictable economic and market conditions. Additionally, rising costs of goods and services purchased by us, including raw materials used in manufacturing our tests, may have an adverse effect on our gross margins and profitability in future periods. If economic and market conditions continue to deteriorate or do not improve, it may make any necessary debt or equity financing more difficult to complete, more costly and more dilutive to our stockholders. Failure to secure any necessary

financing in a timely manner or on favorable terms could have a material adverse effect on our financial performance and stock price or could require us to delay or abandon development other business plans. In addition, there is a risk that one or more of our current and future service providers, manufacturers, suppliers, other partners could be negatively affected by such difficult economic factors, which could adversely affect our ability to attain our operating goals on schedule and on budget or meet our business and financial objectives.

Our success depends upon our ability to adapt to a changing market and our continued development of additional tests and services.

Although we believe that we will provide a competitive range of tests and services, there can be no assurance of acceptance by the marketplace. The procurement of new contracts by us may be dependent upon the continuing results achieved with current and future customers, upon pricing and operational considerations, as well as the potential need for continuing improvement to existing products and services. Moreover, the markets for such services may not develop as expected nor can there be any assurance that we will be successful in our marketing of any such products and services.

Compliance with changing regulation of corporate governance and public disclosure will result in significant additional expenses.

Changing laws, regulations, and standards relating to corporate governance and public disclosure for public companies, including the Sarbanes-Oxley Act of 2002 and various rules and regulations adopted by the SEC, are creating uncertainty for public companies. Our management will need to invest significant time and financial resources to comply with both existing and evolving requirements for public companies, which will lead, among other things, to significantly increased general and administrative expenses and a certain diversion of management time and attention from revenue generating activities to compliance activities.

Risks Related to our Business Operations

We could experience losses or liability not covered by insurance.

Our business exposes us to risks that are inherent in the provision of testing services that assist clinical decision-making. If customers or customer personnel assert liability claims against us, any ensuing litigation, regardless of outcome, could result in a substantial cost to the Company, divert management's attention from operations, and decrease market acceptance of our solutions. The limitations of liability set forth in any contracts we may enter into now or in the future may not be enforceable or may not otherwise protect us from liability for damages. Additionally, we may be subject to claims that are not explicitly covered by a contract. We also maintain general liability coverage; however, this coverage may not continue to be available on acceptable terms, may not be available in sufficient amounts to cover one or more large claims against us, and may include larger self-insured retentions or exclusions for certain products. In addition, the insurer might disclaim coverage as to any future claim. A successful claim not fully covered by our insurance could have a material adverse impact on our liquidity, financial condition, and results of operations.

Our future growth could be harmed if we lose the services of our key personnel.

We are highly dependent upon the talents and services of a number of key employees, specifically Meeshanthini Dogan, PhD and Robert Philibert, MD PhD and other senior technical and management personnel, including our other executive officers, all of whom would be difficult to replace. In 2022, we entered into multi-year employment agreements with each of our executive officers and a consulting agreement with our non-executive chairman. The loss of the services of one or more of these key employees would disrupt our business and harm its results of operations. As competition is intense for the type of highly skilled scientific and medical professionals our business requires, we may not be able to successfully attract and retain senior leadership necessary to grow our business.

If we are unable to hire, retain and motivate qualified personnel, our business will suffer.

Our future success depends, in part, on our ability to continue to attract and retain highly skilled personnel. we believe that there is, and will continue to be, intense competition for highly skilled management, medical, engineering, data science, sales and other personnel with experience in our industry. We must provide competitive compensation packages and a high-quality work environment to hire, retain and motivate employees. If we are unable to retain and motivate our existing employees and attract qualified personnel to fill key positions, we may be unable to manage our business effectively, including the development, marketing and sale of our products, which could adversely affect our business, results of operations and financial condition. To the extent we hire personnel from competitors, we also may be subject to allegations that they have been improperly solicited or that they have divulged proprietary or other confidential information. If we are unable to retain our employees, our business, results of operations and financial condition could be adversely affected.

If we cannot maintain our corporate culture as it grows, we could lose the innovation, teamwork, passion and focus on execution that it believes contribute to its success, and its business may be harmed.

We believe that our corporate culture is a critical component to our success. We have and will continue to invest substantial time and resources in building our team. As we grow and develop the infrastructure of a public company, we may find it difficult to maintain our corporate culture. Any failure to preserve our culture could negatively affect our future success, including our ability to retain and recruit personnel and effectively focus on and pursue our corporate objectives.

We may be unable to manage our growth.

Currently, we have less than 10 full and part-time employees. Our ability to manage our growth effectively will require us to continue to improve our operational, financial and management controls and information systems to accurately forecast sales demand, to manage our operating costs, manage our marketing programs in conjunction with an emerging market, and attract, train, motivate and manage our employees effectively. Our growth strategy will place significant demands on our management team and our financial, administrative and other resources. Operating results will depend substantially on the ability of our officers and key employees to manage changing business conditions and to implement and improve its financial, administrative and other resources. If management fails to manage the expected growth, our results of operations, financial condition, business and prospects could be adversely affected. In addition, our growth strategy may depend on effectively integrating future entities, which requires cooperative efforts from the managers and employees of the respective business entities. If we are unable to respond to and manage changing business conditions, or the scale of our operations, then the quality of our products and services, our ability to retain key personnel, and our business could be harmed, which in turn, could adversely affect our results of operations, financial condition, business and prospects.

Our Board of Directors may change its strategies, policies, and procedures without stockholder approval, and we may become highly leveraged, which may increase our risk of default under our existing or future obligations.

Our investment, financing, leverage, and dividend policies, and our policies with respect to all other activities, including growth, capitalization, and operations, are determined exclusively by our board of directors, and may be amended or revised at any time by our board of directors without notice to or a vote of our stockholders. This could result in the Company conducting operational matters, making investments, or pursuing different business or growth strategies than those contemplated in this Annual Report on Form 10-K. Further, our charter and bylaws do not limit the amount or percentage of indebtedness, funded or otherwise, that we may incur. High leverage also increases the risk of default on our obligations. In addition, a change in our investment policies, including the manner in which we allocate our resources across our portfolio or the types of assets in which we seek to invest, may increase our exposure to interest rate risk and liquidity risk. Changes to our policies with regards to the foregoing could materially adversely affect our financial condition, results of operations, and cash flow.

Our business is subject to the risks of earthquakes, fire, floods, pandemics and other natural catastrophic events, and to interruption by man-made problems, such as power disruptions, computer viruses, data security breaches or terrorism.

A significant natural disaster, such as a tornado, hurricane or a flood, occurring at our headquarters or where a business partner is located could adversely affect our business, results of operations and financial condition. Further, if a natural disaster or man-made problem were to affect our network service providers or Internet service providers, this could adversely affect the ability of our customers to use our products and platform. In addition, health epidemics or pandemics, natural disasters and acts of terrorism could cause disruptions in our business, or the businesses of our customers or service providers. We also rely, and will continue to rely, on our network and third-party infrastructure and enterprise applications and internal technology systems for our engineering, sales and marketing and operations activities. In the event of a major disruption caused by a health epidemic or pandemic, natural disaster or man-made problem, we may be unable to continue our operations and may endure system interruptions, reputational harm, delays in our development activities, lengthy interruptions in service, breaches of data security and loss of critical data, any of which could adversely affect our business, results of operations and financial condition.

We may need to seek alternative business opportunities and change the nature of our business.

As a company in the early stages of its development, we continuously reevaluate our business, the market in which we operate and potential new opportunities. We may seek

other alternatives within the healthcare field in order to grow our business and increase revenues. Such alternatives may include, but not be limited to, combinations or strategic partnerships with laboratory companies or with medical practices such as hospitalists or behavioral health. Pursuing alternative business opportunities could increase our expenses, may require us to obtain additional financing, which may not be available on favorable terms or at all, and result in potentially dilutive issuances of our equity securities or the incurrence of debt that may be burdensome to service, any of which could have a material adverse effect on our business and operations. In addition, pursuing alternative business opportunities may never be successful and may divert significant management time and attention. Moreover, accomplishing and integrating any business opportunity that is pursued by us may disrupt the existing business and may be a complex, risky and costly endeavor and could have a material adverse effect on our business, results of operations, financial condition and prospects.

Any legal proceedings or claims against us could be costly and time-consuming to defend and could harm our reputation regardless of the outcome.

We may in the future become subject to legal proceedings and claims that arise in the ordinary course of business, including intellectual property, collaboration, licensing agreement, product liability, employment, class action, whistleblower and other litigation claims, and governmental and other regulatory investigations and proceedings. Such matters can be time-consuming, divert management's attention and resources, cause us to incur significant expenses or liability, or require us to change our business practices. In addition, the expense of litigation and the timing of this expense from period to period are difficult to estimate, subject to change, and could adversely affect our financial condition and results of operations. Because of the potential risks, expenses, and uncertainties of litigation, we may, from time to time, settle disputes, even where we have meritorious claims or defenses, by agreeing to settlement agreements. Any of the foregoing could adversely affect our business, financial condition, and results of operations.

Risks Related to our Intellectual Property

Our license agreement with the University of Iowa Research Foundation includes a non-exclusive license of "technical information" that potentially could grant unaffiliated third parties access to materials and information considered derivative work made by us, which could be used by such licensees to develop competitive products.

The University of Iowa Research Foundation, or UIRF, license agreement grants to us a worldwide, exclusive, non-transferable license under the Patent Rights, as defined in the agreement, to make, have made, use, sell, offer for sale and import the Licensed Products(s) and/or Licensed Processes, as defined in the agreement, in the field of research tools and clinical diagnostics for cardiovascular disease, stroke, congestive heart failure and diabetes in humans. However, the agreement also confers a non-exclusive license as to Technical Information. Technical Information is defined as certain research and development information, materials, confidential information, technical data, unpatented inventions, know-how and supportive information owned and controlled by the licensor that was not in the public domain as of May 2, 2017 and that describes the Invention, as defined in the agreement, its manufacture and/or use and selected by the licensor to provide to us for use in or with the development, manufacture or use of the Licensed Products and/or Licensed Processes. Technical Information further includes materials, all progeny and derivatives of the materials made by us or our sublicensees, as well as software or other copyrightable work, all derivatives of such software and other copyrightable work made by us and our sublicensees. The ability of UIRF to grant non-exclusive licenses to third parties in and to this broad definition of Technical Information raises the possibility that unaffiliated third parties could use such Technical Information, including Technical Information used by the Company, to make, use, sell, offer to sell and import products and/or processes that compete with the Company's exclusively-licensed products and/or processes or are positioned in markets that the Company may enter in the future. Increased competition could result in reduced demand for the Company's products and/or processes, slow its growth and materially adversely affect its business, operating results and financial condition.

We could incur substantial costs in protecting or defending our intellectual property rights, and any failure to protect or defend our intellectual property could adversely affect our business, results of operations and financial condition.

Our success depends, in part, on our ability to protect our brand and the proprietary methods and technologies that we develop under patent and other intellectual property laws of the United States and foreign jurisdictions so that we can prevent others from using our inventions and proprietary information. Any patents that have been issued or that may be issued in the future may not provide significant protection for our intellectual property. If we fail to protect our intellectual property rights adequately, our competitors might gain access to our technology and our business, results of operations and financial condition may be adversely affected.

The particular forms of intellectual property protection that we seek, or our business decisions about when to file patent applications and trademark applications, may not be adequate to protect our business. We could be required to expend significant resources to monitor and protect our intellectual property rights. Litigation may be necessary in the future to enforce our intellectual property rights, determine the validity and scope of our proprietary rights or those of others, or defend against claims of infringement or invalidity. Such litigation could be costly, time-consuming and distracting to management, result in a diversion of significant resources, lead to the narrowing or invalidation of portions of our intellectual property and have an adverse effect on our business, results of operations and financial condition. Our efforts to enforce our intellectual property rights may be met with defenses, counterclaims and countersuits attacking the validity and enforceability of our intellectual property rights or alleging that we infringe the counterclaimant's own intellectual property. Any of our patents, copyrights, trademarks or other intellectual property rights could be challenged by others or invalidated through administrative process or litigation.

We also rely, in part, on confidentiality agreements with our business partners, employees, consultants, advisors, customers and others in our efforts to protect our proprietary technology, processes and methods. These agreements may not effectively prevent disclosure of our confidential information, and it may be possible for unauthorized parties to copy our software or other proprietary technology or information, or to develop similar technology independently without our having an adequate remedy for unauthorized use or disclosure of our confidential information. In addition, others may independently discover our trade secrets and proprietary information, and in these cases, we would not be able to assert any trade secret rights against those parties. Costly and time-consuming litigation could be necessary to enforce and determine the scope of our proprietary rights, and the failure to obtain or maintain trade secret protection could adversely affect our competitive business position.

In addition, the laws of some countries do not protect intellectual property and other proprietary rights to the same extent as the laws of the United States. To the extent we expand into international activities, our exposure to unauthorized copying, transfer and use of our proprietary technology or information may increase.

Our means of protecting our intellectual property and proprietary rights may not be adequate or our competitors could independently develop similar technology. If we fail to meaningfully protect our intellectual property and proprietary rights, our business, results of operations and financial condition could be adversely affected.

Assertions by third parties of infringement or other violations by us of its intellectual property rights could result in significant costs and harm our business and operating results.

Our success depends upon our ability to refrain from infringing upon the intellectual property rights of others. Some companies, including some of our competitors, own large numbers of patents, copyrights and trademarks, which they may use to assert claims against us. As we grow and enter new markets, we will face a growing number of competitors. As the number of competitors in our industry grows and the functionality of products in different industry segments overlaps, we expect that software and other solutions in our industry may be subject to such claims by third parties. Third parties may in the future assert claims of infringement, misappropriation or other violations of intellectual property rights against us. We cannot assure investors that infringement claims will not be asserted against us in the future, or that, if asserted, any infringement claim will be successfully defended. A successful claim against us could require that we pay substantial damages or ongoing royalty payments, prevent us from offering our products and services, or require that we comply with other unfavorable terms. We may also be obligated to indemnify our customers or business partners or pay substantial settlement costs, including royalty payments, in connection with any such claim or litigation and to obtain licenses, modify applications or refund fees, which could be costly. Even if we were to prevail in such a dispute, any litigation regarding our intellectual property could be costly and time-consuming and divert the attention of our management and key personnel from our business operations.

Certain of our core technology is licensed, and that license may be terminated if we were to breach our obligations under the license.

The initial work on our core technology is derived from work done by our founders while at the University of Iowa, around which there is currently a family of patent applications, the rights of which are owned by the University of Iowa Research Foundation (UIRF) and exclusively licensed to us. In addition, certain follow-on work on our core technology also is derived from work done by our founders while at the University of Iowa but was furthered by our founders. Therefore, certain follow-on work is co-owned by UIRF and us, and exclusively licensed to us under the license agreement with UIRF. That license agreement and those licenses granted under the license agreement terminate on the expiration of the patent rights licensed under the license agreement, unless certain proprietary, non-patented technical information is still being used by us, in which case the license agreement will not terminate until the date of termination of such use. The licenses under the license agreement could terminate prior to the expiration of the licensed patent rights if we materially breach our obligations under the license agreement, including failing to pay the applicable license fees and any interest on such fees, and if we fail to fully remedy such breach within the period specified in the license agreement, or if we enter liquidation, have a receiver or administrator appointed over any assets related to the license agreement, or cease to carry on business, or file for bankruptcy or if an involuntary bankruptcy petition is filed against us. The license agreement can also be terminated by UIRF as a result of our failure to timely achieve certain performance goals, including minimum requirements for commercial sales of our cardiac test, provided that UIRF first provides written notice to us of such failure and if such failure is not remedied within 90 days following any such notice.

Some of our technologies incorporate "open-source" software or other similar licensed technologies, which could become unavailable or subject us to increased costs, delays in production or assessment or litigation.

In order to provide our products, we currently use a variety of technologies including, for example, genotyping, digital methylation assessment and data processing technologies owned by third parties. The terms of these agreements, and any other "open source" software agreements we may rely upon in the future, are subject to change without notice and may increase our costs. Moreover, our failure to comply with the terms of one or more of these agreements could expose us to business disruption because the license may be terminated automatically due to non-compliance.

The use and distribution of open-source software may also entail greater risks than the use of third-party commercial software, as open-source licensors generally do not provide warranties or other contractual protections regarding infringement claims or the quality of the code. Many of the risks associated with use of open-source software cannot be eliminated and could negatively affect our business.

In addition, the wide availability of open-source code used in our current and future products could expose us to security vulnerabilities. From time to time, we may face claims from third parties asserting ownership of, or demanding release of, the open-source software or derivative works that we developed using such software (which could include our proprietary source code), or otherwise seeking to enforce the terms of the applicable open-source license. These claims could result in litigation that could be costly to defend, have a negative effect on our operating results and financial condition or require us to devote additional research and development resources to change our existing or future proprietary source code. Responding to any infringement or noncompliance claim by an open-source vendor, regardless of its validity, discovering certain open-source software code in our products, or a finding that we have breached the terms of an open-source software license, could harm our business, results of operations and financial condition. In each case, we would be required to either seek licenses to software or services from other parties and redesign our products to function with such other parties' software or services or develop these components internally, which would result in increased costs and could result in delays to product launches. Furthermore, we might be forced to limit the features available in our current or future solutions. If these delays and feature limitations occur, our business, results of operations and financial condition could be adversely affected.

Intellectual property that is in-licensed may have been made using government funding and, thus, may be subject to federal regulations under the Bayh-Dole Act.

The intellectual property Cardio has licensed from UIRF is indicated as having been discovered through government funded programs and thus, may be subject to federal regulations under the Bayh-Dole Act. In general, the Bayh-Dole Act provides the U.S. government certain rights in inventions developed using government funding, such as a right to a non-exclusive, non-transferable, irrevocable worldwide license to use inventions for any governmental purpose. In addition, intellectual property generated with government funding is also subject to certain reporting requirements, and the Bayh-Dole Act requires that any products subject to the Bayh-Dole Act be manufactured substantially in the United States, although this manufacturing requirement can be waived if the owner of the patents and applications can show that reasonable efforts to manufacture the product substantially in the United States were unsuccessful, or that under the circumstances, domestic manufacture is not commercially feasible.

Under the Bayh-Dole Act, the U.S. government has the right to take title to inventions developed using a U.S. government funded program, referred to as "march-in rights," for a number of reasons including, for example, failure to disclose the invention to the government or failure to file an application within specified time limits. In addition, under the Bayh-Dole Act, the U.S. government has the right to require any invention developed using U.S. government funding to be granted exclusive, partially exclusive, or non-exclusive licenses to any of these inventions to a third party if it determines that (i) adequate steps have not been taken to commercialize the invention (ii) government action is necessary to meet public health or safety needs or (iii) government action is necessary to meet requirements for public use under federal regulations.

Compliance with such regulations may limit Cardio's exclusive rights, subject Cardio to expenditure of resources with respect to reporting requirements and limit Cardio's ability to contract with non-U.S. manufacturers. In addition, any exercise by the government of any of the foregoing rights under the Bayh-Dole Act may affect Cardio's competitive position, business, financial condition, results of operations, and prospects.

Risks Related to Government Regulation

We conduct business in a heavily regulated industry, and if we fail to comply with these laws and government regulations, we could incur penalties or be required to make significant changes to our operations or experience adverse publicity, which could have a material adverse effect on our business, financial condition, and results of operations.

The healthcare industry is heavily regulated and closely scrutinized by federal, state and local governments. Comprehensive statutes and regulations govern the manner in which we provide and bill for our products services and collect reimbursement from governmental programs and private payors, our contractual relationships with providers, vendors and customers, our marketing activities and other aspects of our operations. Of particular importance are:

- the federal physician self-referral law, commonly referred to as the Stark Law;
- the federal Anti-Kickback Act;
- the criminal healthcare fraud provisions of HIPAA;
- the federal False Claims Act;
- reassignment of payment rules that prohibit certain types of billing and collection;
- similar state law provisions pertaining to anti-kickback, self-referral and false claims issues;
- state laws that prohibit general business corporations, such as us, from practicing medicine; and
- laws that regulate debt collection practices as applied to our debt collection practices.

Because of the breadth of these laws and the narrowness of the statutory exceptions and safe harbors available, it is possible that some of our business activities could be subject to challenge under one or more of such laws. Achieving and sustaining compliance with these laws may prove costly. Failure to comply with these laws and other laws can result in civil and criminal penalties such as fines, damages, overpayment recoupment loss of enrollment status and exclusion from the Medicare and Medicaid programs. The risk of us being found in violation of these laws and regulations is increased by the fact that many of them have not been fully interpreted by the regulatory authorities or the courts, and their provisions are sometimes open to a variety of interpretations. Our failure to accurately anticipate the application of these laws and regulations to our business or any other failure to comply with regulatory requirements could create liability for us and negatively affect our business. Any action against us for violation of these laws or regulations, even if we successfully defend against it, could cause us to incur significant legal expenses, divert management's attention from the operation of our business and result in loss of customers and adverse publicity.

To enforce compliance with the federal laws, the U.S. Department of Justice and the Office of the Inspector General (OIG) have recently increased their scrutiny of healthcare providers, which has led to a number of investigations, prosecutions, convictions and settlements in the healthcare industry. Dealing with investigations can be time- and resource-consuming and can divert management's attention from the business. Any such investigation or settlement could increase our costs or otherwise have an adverse effect on our business. In addition, because of the potential for large monetary exposure under the federal False Claims Act, which provides for treble damages and mandatory minimum penalties of $5,500 to $11,000 per false claim or statement, healthcare providers often resolve allegations without admissions of liability for significant and material amounts to avoid the uncertainty of treble damages that may be awarded in litigation proceedings. Such settlements often contain additional compliance and reporting requirements as part of a consent decree, settlement agreement or corporate integrity agreement. Given the significant size of actual and potential settlements, it is expected that the government will continue to devote substantial resources to investigating healthcare providers' compliance with the healthcare reimbursement rules and fraud and abuse laws.

The laws, regulations and standards governing the provision of healthcare services may change significantly in the future. We cannot assure investors that any new or changed healthcare laws, regulations or standards will not materially adversely affect our business. We cannot assure investors that a review of our business by judicial, law enforcement, regulatory or accreditation authorities will not result in a determination that could adversely affect our operations.

If the U. S. Food and Drug Administration (the "FDA") were to begin actively regulating our tests, we could incur substantial costs and delays associated with trying to obtain premarket clearance or approval and incur costs associated with complying with post-market controls.

We believe our Epi+Gen CHD™ and PrecisionCHD™ tests are LDTs. The FDA generally considers an LDT to be a test that is designed, manufactured, and used within a single laboratory that is certified under CLIA and meets the regulatory requirements under CLIA to perform high complexity testing. The FDA sometimes determines that a test that is being offered by a laboratory as an LDT is not an LDT under the FDA's interpretation of that term but is an in IVD product in commercial distribution, and therefore must comply

with the regulations that apply to IVDs, including the need for successfully completing the FDA review process. If the FDA were to conclude that our test is not an LDT, we would be subject to extensive regulation as a medical device.

For tests that are deemed to be LDTs, the FDA has historically taken the position that it has the authority to regulate such tests as IVDs under the Federal Food, Drug, and Cosmetic Act ("FDC Act"), although it has generally exercised enforcement discretion with regard to LDTs. This means that even though the FDA believes it can impose regulatory requirements on LDTs, such as requirements to obtain premarket approval, de novo authorization or clearance of LDTs, it has generally chosen not to enforce those requirements. Various bills have been introduced in Congress seeking to substantially revamp the regulation of both LDTs and IVDs. In March 2020, the Verifying Accurate, Leading-edge IVCT Development ("VALID") Act of 2020 was introduced in the Senate, which proposed a risk-based regulatory framework for IVDs and LDTs and required premarket approval for some in vitro clinical tests. The VALID Act was reintroduced in June 2021 and again most recently in March 2023; the prospects for enactment are uncertain. In March 2020, the Verified Innovative Testing in American Laboratories ("VITAL") Act of 2020 was introduced in the Senate, which would expressly shift the regulation of LDTs from FDA to CMS. The VITAL Act was reintroduced in May 2021, and has not since been reintroduced. Neither the VALID Act nor the VITAL Act has been enacted into law as of the date of this Annual Report on Form 10-K.

In the meantime, the regulation by the FDA of LDTs remains uncertain. In September 2023, the FDA announced a proposed regulation that would, if adopted, alter the FDA's historical exercise of enforcement discretion for LDTs by classifying LDTs as medical devices. The proposed regulation would subject LDTs to a more stringent regulatory framework, including premarket clearance or approval requirements, QSR, and post-market surveillance obligations. Failure to comply with these and other FDA regulations could result in legal actions, including fines and penalties. The FDA has indicated it plans to finalize the proposed rule in the second quarter of 2024, though it is uncertain whether the FDA will finalize the proposed rule on this timeline or at all or whether there would be litigation challenging the final rule. If the FDA premarket clearance, approval or authorization is required by FDA for any of our existing or future tests, or for any components or materials we use in our tests, such as the component used to collect samples from patients, we would need to submit a premarket notification, PMA application or request for de novo authorization to the FDA and to include information supporting our LDT. For example, the regulatory premarket clearance, approval or de novo authorization process may involve, among other things, successfully completing analytical, pre-clinical and/or clinical studies beyond the studies we have already performed or plan to perform for our LDT. These studies may be extensive and costly and may take a substantial period of time to complete. Any such studies may fail to generate data that meets the FDA's requirements. The studies may also not be conducted in a manner that meets the FDA's requirements, and therefore could not support the marketing application. There can be no assurance that the submission of such an application will result in a timely response by the FDA or a favorable outcome that will allow the test to be marketed. In addition, we may be forced to stop selling our tests or we may be required to modify claims for or make other changes to our tests while we work to obtain FDA clearance, approval or de novo authorization. Our business may be adversely affected while such review is ongoing and if we are ultimately unable to obtain premarket clearance, approval or de novo authorization.

Certain types of standalone diagnostics device software functions are subject to FDA regulation as a medical device. Some types of device software functions are subject to premarket requirements. If the FDA were to conclude that Cardio or our licensee is required to obtain premarket authorization for the software used in Epi+Gen CHD™ or PrecisionCHD™, our ability to offer the tests as an LDT could be delayed or prevented, which would adversely affect our business.

In addition, we may require cooperation in our filings for FDA clearance, approval or de novo authorization from third-party manufacturers of the components of our tests. We cannot be certain that we will receive the support we need from third-party vendors in a timely fashion, or that the information they provide will meet FDA's requirements.

We cannot assure investors that any of our tests for which we decide to pursue or are required to obtain premarket clearance, approval or de novo authorization by the FDA will be cleared, approved or authorized on a timely basis, if at all. In addition, if a test has been cleared, approved or authorized, certain kinds of changes that we may make, *e.g.*, to improve the test, or because of issues with suppliers of the components of the test or modification by a supplier to a component upon which our test approval relies, may result in the need for the test to obtain new clearance, approval or authorization from the FDA before we can implement them. Ongoing compliance with FDA regulations, such as the QSR, labeling requirements, Medical Device Reports, and recall reporting, would increase the cost of conducting our business. We will be subject to periodic inspection by the FDA to ascertain whether our facility does comply with applicable requirements. The penalties for failure to comply with these FDA requirements may include Warning Letters, product seizure, injunctions, civil penalties, criminal penalties, mandatory customer notification, and recalls, any of which may adversely impact our business and results of operations.

Furthermore, the FDA or the Federal Trade Commission ("FTC"), as well as state consumer protection agencies, may object to the materials and methods we use to promote the use of our current tests or other tests we may develop in the future, including with respect to the product claims in our promotional materials, and may initiate enforcement actions against us. Enforcement actions by these agencies may include, among others, injunctions, civil penalties, fines, and equitable monetary relief.

If our products do not receive adequate coverage and reimbursement from third-party payors, our ability to expand access to our tests beyond the initial sales channels will be limited and our overall commercial success will be limited.

We currently do not have broad-based coverage and reimbursement for the Epi+Gen CHD™ and PrecisionCHD™ tests. However, our strategy is to expand access to our tests by pursuing coverage and reimbursement by third-party payors, including government payors. Coverage and reimbursement by third-party payors, including managed care organizations, private health insurers, and government healthcare programs, such as Medicare and Medicaid in the United States and similar programs in other countries, for the types of risk assessment and detection tests we perform can be limited and uncertain. Healthcare providers may not order our products unless third-party payors cover and provide adequate reimbursement for a substantial portion of the price of the products. If we are not able to obtain adequate coverage and an acceptable level of reimbursement for our products from third-party payors, there could be a greater co-insurance or co-payment obligation for any individual for whom a test is ordered. The individual may be forced to pay the entire cost of a test out-of-pocket, which could dissuade physicians from ordering our products and, if ordered, could result in delay in or decreased likelihood of collection of payment.

Medicare is the single largest U.S. payor and a particularly important payor for many cardiac-related laboratory services, given the demographics of the Medicare population. Generally, traditional Medicare fee-for-service will not cover screening tests that are performed in the absence of signs, symptoms, complaints, personal history of disease, or injury except when there is a statutory provision that explicitly covers the test. Epi+Gen CHD™ could be considered a screening test under Medicare and, accordingly, may not be eligible for traditional Medicare fee-for-service coverage and reimbursement unless we pursue substantial additional measures, which would require significant investments, and may ultimately be unsuccessful or may take several years to achieve.

If eligible for reimbursement, laboratory tests such as ours generally are classified for reimbursement purposes under CMS's Healthcare Common Procedure Coding System ("HCPCS") and the American Medical Association's ("AMA") Current Procedural Terminology ("CPT") coding systems. We and payors must use those coding systems to bill and pay for our diagnostic tests, respectively. These HCPCS and CPT codes are associated with the particular product or service that is provided to the individual. Accordingly, without a HCPCS or CPT code applicable to our products, the submission of claims could be a significant challenge. Once CMS creates an HCPCS code or the AMA establishes a CPT code, CMS establishes payment rates and coverage rules under traditional Medicare, and private payors establish rates and coverage rules independently. Under Medicare, payment for laboratory tests is generally made under the Clinical Laboratory Fee Schedule ("CLFS") with payment amounts assigned to specific HCPCS and CPT codes. In addition, effective January 1, 2018, a new Medicare payment methodology went into effect for clinical laboratory tests, under which laboratory-reported private payor rates are used to establish Medicare payment rates for tests reimbursed via the CLFS. The new methodology implements Section 216 of the Protecting Access to Medicare Act of 2014 ("PAMA") and requires laboratories that meet certain requirements related to volume and type of Medicare revenues to report to CMS their private payor payment rates for each test they perform, the volume of tests paid at each rate, and the HCPCS code associated with the test. CMS uses the reported information to set the Medicare payment rate for each test at the weighted median private payor rate. The full impact of the PAMA rate-setting methodology and its applicability to our products remains uncertain at this time.

Coverage and reimbursement by a third-party payor may depend on a number of factors, including a payor's determination that a product is appropriate, medically necessary, and cost-effective. Each payor will make its own decision as to whether to establish a policy or enter into a contract to cover our products and the amount it will reimburse for such products. Obtaining approvals from third-party payors to cover our products and establishing adequate coding recognition and reimbursement levels is an unpredictable, challenging, time-consuming, and costly process, and we may never be successful. If third-party payors do not provide adequate coverage and reimbursement for our products, our ability to succeed commercially will be limited.

Even if we establish relationships with payors to provide our products at negotiated rates, such agreements would not obligate any healthcare providers to order our products or guarantee that we would receive reimbursement for our products from these or any other payors at adequate levels. Thus, these payor relationships, or any similar relationships, may not result in acceptable levels of coverage and reimbursement for our products or meaningful increases in the number of billable tests we sell to healthcare providers. We believe it may take at least several years to achieve coverage and adequate reimbursement with a majority of third-party payors, including with those payors offering negotiated rates. In addition, we cannot predict whether, under what circumstances, or at what payment levels payors will cover and reimburse for our products. We do not expect Epi+Gen CHD™ or PrecisionCHD™ to have Medicare or other third-party coverage or reimbursement in the near term. However, if we fail to establish and maintain broad-based coverage and reimbursement for our products, our ability to expand access to our products, generate increased revenue, and grow our test volume and customer base will be limited, and our overall commercial success will be limited.

Our products may fail to achieve the degree of market acceptance necessary for commercial success.

The failure of our products, once introduced, to be listed in physician guidelines or of our studies to produce favorable results or to be published in peer-reviewed journals could limit the adoption of our products. In addition, healthcare providers and third-party payors, including Medicare, may rely on physician guidelines issued by industry groups, medical societies, and other key organizations, before utilizing or reimbursing the cost of any diagnostic or screening test. Although we have published a study showing the Epi+Gen CHD™ and PrecisionCHD™ tests are associated with cost saving, it is not yet, and may never be, listed in any such guidelines.

Further, if our products or the technology underlying them do not receive sufficient favorable exposure in peer-reviewed publications, the rate of physician and market acceptance of our products and positive reimbursement coverage decisions for our products could be negatively affected. The publication of clinical data in peer-reviewed journals is an important step in commercializing and obtaining reimbursement for products, such as Epi+Gen CHD™ and PrecisionCHD™, and our inability to control when, if ever, results are published may delay or limit our ability to derive sufficient revenues from any product that is developed using data from a clinical study.

Failure to achieve broad market acceptance of our products, including Epi+Gen CHD™ and PrecisionCHD™, would materially harm our business, financial condition, and results of operations.

Risks Related to Customer Privacy, Cybersecurity and Data

Our use and disclosure of personally identifiable information, including health information, is subject to federal and state privacy and security regulations, and our failure to comply with those regulations or to adequately secure the information we hold could result in significant liability or reputational harm and, in turn, a material adverse effect on our customer base and revenue.

Numerous state and federal laws and regulations govern the collection, dissemination, use, privacy, confidentiality, security, availability and integrity of Personally Identifiable Information ("PII"), including protected health information. These laws and regulations include the Health Insurance Portability and Accountability Act of 1996 ("HIPAA"). HIPAA establishes a set of basic national privacy and security standards for the protection of protected health information, ("PHI"), by health plans, healthcare clearinghouses and certain healthcare providers, referred to as covered entities, and the business associates with whom such covered entities contract for services, which includes Cardio.

HIPAA requires healthcare providers like Cardio to develop and maintain policies and procedures with respect to PHI that is used or disclosed, including the adoption of administrative, physical and technical safeguards to protect such information. HIPAA also implemented the use of standard transaction code sets and standard identifiers that covered entities must use when submitting or receiving certain electronic healthcare transactions, including activities associated with the billing and collection of healthcare claims.

HIPAA imposes mandatory penalties for certain violations. Penalties for violations of HIPAA and its implementing regulations start at $100 per violation and are not to exceed $50,000 per violation, subject to a cap of $1.5 million for violations of the same standard in a single calendar year. However, a single breach incident can result in violations of multiple standards. HIPAA also authorizes state attorneys general to file suit on behalf of their residents. Courts will be able to award damages, costs and attorneys' fees related to violations of HIPAA in such cases. While HIPAA does not create a private right of action allowing individuals to sue us in civil court for violations of HIPAA, its standards have been used as the basis for duty of care in state civil suits such as those for negligence or recklessness in the misuse or breach of PHI.

In addition, HIPAA mandates that the Secretary of Health and Human Services, or HHS, conduct periodic compliance audits of HIPAA-covered entities or business associates for compliance with the HIPAA Privacy and Security Standards. It also tasks HHS with establishing a methodology whereby harmed individuals who were the victims of breaches of unsecured PHI may receive a percentage of the Civil Monetary Penalty fine paid by the violator.

HIPAA further requires that patients be notified of any unauthorized acquisition, access, use or disclosure of their unsecured PHI that compromises the privacy or security of such information, with certain exceptions related to unintentional or inadvertent use or disclosure by employees or authorized individuals. HIPAA specifies that such notifications must be made "without unreasonable delay and in no case later than 60 calendar days after discovery of the breach." If a breach affects 500 patients or more, it must be reported to HHS without unreasonable delay, and HHS will post the name of the breaching entity on its public web site. Breaches affecting 500 patients or more in the same state or jurisdiction must also be reported to the local media. If a breach involves fewer than 500 people, the covered entity must record it in a log and notify HHS at least annually.

Numerous other federal and state laws protect the confidentiality, privacy, availability, integrity and security of personally identifiable information, or PII, including PHI. These laws in many cases are more restrictive than, and may not be preempted by, the HIPAA rules and may be subject to varying interpretations by courts and government agencies, creating complex compliance issues for us, and our customers and potentially exposing us to additional expense, adverse publicity and liability.

New health information standards, whether implemented pursuant to HIPAA, congressional action or otherwise, could have a significant effect on the manner in which we must handle healthcare related data, and the cost of complying with standards could be significant. If we do not comply with existing or new laws and regulations related to PHI, it could be subject to criminal or civil sanctions.

Because of the extreme sensitivity of the PII that we store and transmit, the security features of our technology platform are very important. If our security measures, some of which are managed by third parties, are breached or fail, unauthorized persons may be able to obtain access to sensitive customer and patient data, including HIPAA-regulated PHI. As a result, our reputation could be severely damaged, adversely affecting customer and patient confidence. Customers may curtail their use of or stop using our services or our customer base could decrease, which would cause our business to suffer. In addition, we could face litigation, damages for contract breach, penalties and regulatory actions for violation of HIPAA and other applicable laws or regulations and significant costs for remediation, notification to individuals and for measures to prevent future occurrences. Any potential security breach could also result in increased costs associated with liability for stolen assets or information, repairing system damage that may have been caused by such breaches, incentives offered to customers or other business partners in an effort to maintain our business relationships after a breach and implementing measures to prevent future occurrences, including organizational changes, deploying additional personnel and protection technologies, training employees and engaging third-party experts and consultants. While we maintain insurance covering certain security and privacy damages and claims expenses, we may not carry insurance or maintain coverage sufficient to compensate for all liability and in any event, insurance coverage would not address the reputational damage that could result from a security incident.

We outsource important aspects of the storage and transmission of customer and customer personnel information, a nd thus rely on third parties to manage functions that have material cyber-security risks. We attempt to address these risks by requiring outsourcing subcontractors who handle customer and customer personnel information to sign business associate agreements contractually requiring those subcontractors to adequately safeguard personal health data to the same extent that applies to us and in some cases by requiring such outsourcing subcontractors to undergo third-party security examinations. In addition, we periodically hire third-party security experts to assess and test our security posture. However, we cannot assure investors that these contractual measures and other safeguards will adequately protect us from the risks associated with the storage and transmission of client and patient's proprietary and protected health information.

In addition, U.S. states are adopting new laws or amending existing laws and regulations, requiring attention to frequently changing regulatory requirements applicable to data related to individuals. For example, California has enacted the California Consumer Privacy Act ("CCPA"). The CCPA gives California residents expanded rights to access and delete their personal information, opt out of certain personal information sharing and receive detailed information about how their personal information is used by requiring covered companies to provide new disclosures to California consumers (as that term is broadly defined and which can include any of our current or future employees who may be California residents or any other California residents whose data we collect or process) and provide such residents new ways to opt out of certain sales of personal information. The CCPA provides for civil penalties for violations, as well as a private right of action for data breaches that is expected to increase data breach litigation. As we expand our operations and customer base, the CCPA may increase our compliance costs and potential liability. Additionally, a new privacy law, the California Privacy Rights Act ("CPRA"), was approved by California voters in the election in November 2020. The CPRA created obligations relating to consumer data beginning on January 1, 2022, with implementing regulations originally required to be adopted by July 1, 2022, but which remain in proposed format as of December 6, 2022. Enforcement is to begin July 1, 2023, unless that deadline is extended due to the delay in the adoption of the final regulations. The CPRA modifies the CCPA significantly, potentially resulting in further uncertainty and requiring us to incur additional costs and expenses in an effort to comply. Additionally, other U.S. states continue to propose, and in certain cases adopt, privacy-focused legislation such as Colorado, Virginia, Utah and Connecticut. Aspects of these state laws remain unclear, resulting in further uncertainty and potentially requiring us to modify our data practices and policies and to incur substantial additional costs and expenses in an effort to comply.

Privacy and data security laws and regulations could require us to make changes to our business, impose additional costs on us and reduce the demand for our tests and services.

Our business model contemplates that we will store, process and transmit both public data and our customers' and customer personnel's private data. Our customers may store and/or transmit a significant amount of personal or identifying information through our platform. Privacy and data security have become significant issues in the United States and in other jurisdictions where we may offer our solutions. The regulatory framework relating to privacy and data security issues worldwide is evolving rapidly and is likely to remain uncertain for the foreseeable future. Federal, state and foreign government bodies and agencies have in the past adopted, or may in the future adopt, laws and regulations regarding the collection, use, processing, storage and disclosure of personal or identifying information obtained from customers and other individuals. In addition to government regulation, privacy advocates and industry groups may propose various self-regulatory standards that may legally or contractually apply to our business. Because the interpretation and application of many privacy and data security laws, regulations and applicable industry standards are uncertain, it is possible that these laws, regulations and standards may be interpreted and applied in a manner inconsistent with our existing privacy and data management practices. As we expand into new jurisdictions or verticals, we

will need to understand and comply with various new requirements applicable in those jurisdictions or verticals.

To the extent applicable to our business or the businesses of our customers, these laws, regulations and industry standards could have negative effects on our business, including by increasing our costs and operating expenses, and delaying or impeding our deployment of new core functionality and products. Compliance with these laws, regulations and industry standards requires significant management time and attention, and failure to comply could result in negative publicity, subject us to fines or penalties or result in demands that we modify or cease existing business practices. In addition, the costs of compliance with, and other burdens imposed by, such laws, regulations and industry standards may adversely affect our customers' ability or desire to collect, use, process and store personal information using our solutions, which could reduce overall demand for them. Even the perception of privacy and data security concerns, whether or not valid, may inhibit market acceptance of our solutions in certain verticals. Furthermore, privacy and data security concerns may cause our customers' customers, vendors, employees and other industry participants to resist providing the personal information necessary to allow our customers to use our applications effectively. Any of these outcomes could adversely affect our business and operating results.

General Risks Affecting Our Company

A pandemic, epidemic or outbreak of an infectious disease in the United States or worldwide, including the outbreak of the novel strain of coronavirus disease, COVID-19, could adversely affect our business.

If a pandemic, epidemic or outbreak of an infectious disease occurs in the United States or worldwide, our business may be adversely affected. If the COVID-19 virus and its potentially more contagious variants cause an additional resurgence of infection of COVID-19, or if new variants continue to develop resistance to government approved COVID-19 vaccinations, or if an influenza or other pandemic were to occur, our business, results of operations, financial condition and liquidity could be negatively impacted.

As a result of public health emergencies, we experienced, and in the future could experience, supply chain disruptions, including shortages, delays and work stoppages among some vendors and suppliers, travel restrictions and cancellation of events, among other effects, thereby significantly and negatively impacting our operations. In addition, our results and financial condition may be adversely affected by future federal or state laws, regulations, orders, or other governmental or regulatory actions addressing public health emergencies such as a COVID-19 or the U.S. health care system, which, if adopted, could result in direct or indirect restrictions to its business, financial condition, results of operations and cash flow.

Changes in accounting standards and subjective assumptions, estimates and judgments by management related to complex accounting matters could significantly affect our financial results or financial condition.

Generally accepted accounting principles and related accounting pronouncements, implementation guidelines and interpretations with regard to a wide range of matters that are relevant to our business, including but not limited to revenue recognition, allowance for doubtful accounts, content asset amortization policy, valuation of our Common Stock, stock-based compensation expense and income taxes, are highly complex and involve many subjective assumptions, estimates and judgments. Changes in these rules or their interpretation or changes in underlying assumptions, estimates or judgments could significantly change or increase volatility of our reported or expected financial performance or financial condition. Refer to Note 3, "Summary of Significant Accounting Policies" to the Audited Financial Statements included elsewhere in this Annual Report on Form 10-K for a description of recent accounting pronouncements.

Risks Related to Our Securities

We are an "emerging growth company" and "smaller reporting company" within the meaning of the Securities Act, and if we take advantage of certain exemptions from disclosure requirements available to emerging growth companies, it could make our securities less attractive to investors and may make it more difficult to compare our performance to the performance of other public companies.

We are an "emerging growth company" as defined in Section 2(a)(19) of the Securities Act, as modified by the JOBS Act. As such, we are eligible for and intend to take advantage of certain exemptions from various reporting requirements applicable to other public companies that are not emerging growth companies for as long as we continue to be an emerging growth company, including, but not limited to, (a) not being required to comply with the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act, (b) reduced disclosure obligations regarding executive compensation in our periodic reports and proxy statements and (c) exemptions from the requirements of holding a nonbinding advisory vote on executive compensation and stockholder approval of any golden parachute payments not previously approved. As a result, our stockholders may not have access to certain information they may deem important. We will remain an emerging growth company until the earliest of (i) the last day of the fiscal year in which the market value of shares of Common Stock that are held by non-affiliates exceeds $700 million as of June 30 of that fiscal year, (ii) the last day of the fiscal year in which we have total annual gross revenue of $1.07 billion or more during such fiscal year (as indexed for inflation), (iii) the date on which we have issued more than $1 billion in non-convertible debt in the prior three-year period or (iv) December 31, 2026, which is the last day of the fiscal year following the fifth anniversary of the date of the first sale of Common Stock in Mana's initial public offering. We cannot predict whether investors will find our securities less attractive because it will rely on these exemptions. If some investors find our securities less attractive as a result of our reliance on these exemptions, the trading prices of our securities may be lower than they otherwise would be, there may be a less active trading market for our securities and the trading prices of our securities may be more volatile.

Further, Section 102(b)(1) of the JOBS Act exempts emerging growth companies from being required to comply with new or revised financial accounting standards until private companies (that is, those that have not had a Securities Act registration statement declared effective or do not have a class of securities registered under the Exchange Act) are required to comply with the new or revised financial accounting standards. The JOBS Act provides that a company can elect to opt out of the extended transition period and comply with the requirements that apply to non-emerging growth companies but any such election to opt out is irrevocable. We have elected not to opt out of such extended transition period, which means that when a standard is issued or revised and it has different application dates for public or private companies, we, as an emerging growth company, can adopt the new or revised standard at the time private companies adopt the new or revised standard. This may make comparison of our financial statements with another public company that is neither an emerging growth company nor an emerging growth company that has opted out of using the extended transition period difficult or impossible because of the potential differences in accounting standards used.

Additionally, we are a "smaller reporting company" as defined in Item 10(f)(1) of Regulation S-K. Smaller reporting companies may take advantage of certain reduced disclosure obligations, including, among other things, providing only two years of audited financial statements. We expect that we will remain a smaller reporting company until the last day of any fiscal year for so long as either (a) the market value of our Common Stock held by non-affiliates does not equal or exceed $250 million as of the prior June 30th, or (b) our annual revenues did not equal or exceed $100 million during such completed fiscal year and the market value of our Common Stock held by non-affiliates did not equal or exceed $700 million as of the prior June 30th. To the extent we take advantage of such reduced disclosure obligations, it may also make comparison of our financial statements with other public companies difficult or impossible.

Our stock price may be volatile and may decline regardless of our operating performance.

The market price of our Common Stock may fluctuate significantly in response to numerous factors and may continue to fluctuate for these and other reasons, many of which are beyond our control, including:

- actual or anticipated fluctuations in our revenue and results of operations;
- failure of securities analysts to maintain coverage of the Company, changes in financial estimates or ratings by any securities analysts who follow us or our failure to meet these estimates or the expectations of investors;
- announcements by us or our competitors of significant technical innovations, acquisitions, strategic partnerships, joint ventures, results of operations or capital commitments;
- changes in operating performance and stock market valuations of other healthcare-related companies generally, or those in the medical diagnostics industry in particular;
- price and volume fluctuations in the overall stock market, including as a result of trends in the economy as a whole;
- trading volume of our Common Stock;
- the inclusion, exclusion or removal of our Common Stock from any indices;
- changes in the Board or management;
- transactions in our Common Stock by directors, officers, affiliates and other major investors;
- lawsuits threatened or filed against us;
- changes in laws or regulations applicable to our business;

- changes in our capital structure, such as future issuances of debt or equity securities;
- short sales, hedging and other derivative transactions involving our capital stock;
- general economic conditions in the United States;
- pandemics or other public health crises, including, but not limited to, the COVID-19 pandemic (including additional variants such as the Omicron variant);
- other events or factors, including those resulting from war, incidents of terrorism or responses to these events; and
- the other factors described in this "Risk Factors" section.

The stock market has recently experienced extreme price and volume fluctuations. The market prices of securities of companies have experienced fluctuations that often have been unrelated or disproportionate to their operating results. In the past, stockholders have sometimes instituted securities class action litigation against companies following periods of volatility in the market price of their securities. Any similar litigation against us could result in substantial costs, divert management's attention and resources, and harm its business, financial condition, and results of operations.

An active trading market for our Common Stock may not be created or sustained.

We have listed our Common Stock and Warrants on Nasdaq under the symbols "CDIO" and "CDIOW," respectively. We cannot assure you that an active trading market for its Common Stock will be created or sustained. Accordingly, we cannot assure you of the liquidity of any trading market, your ability to sell your shares of our Common Stock when desired or the prices that you may obtain for your shares.

Future sales of Common Stock in the public market could cause our share price to decline significantly, even if our business is doing well.

We have filed, and the SEC has declared effective, registration statements covering (i) the resale of Common Stock underlying Public Warrants issued in the Company's initial public offering and a substantial number of shares of Common Stock and shares underlying warrants issued in private placements we completed prior to our Business Combination; (ii) up to $17 million in securities on a shelf registration statement that we are currently using for an at-the-market offering of up to $17 million; and (iii) a registration statement on Form S-8 covering our 2022 Equity Incentive Plan. Public sales of securities can continue to be made under these registration statements. We also plan to file a registration statement covering the resale of Common Stock and shares underlying warrants that we recently sold in a private placement. In addition, all of the shares we issued in the Business Combination to holders of Legacy Cardio securities are available for resale under Rule 144 without restriction, subject to certain limitations that apply to our affiliates.

The total number of shares available for resale under these registration statements and/or under Rule 144 represents a significant percentage of our outstanding shares. The resale, or expected or potential resale, of a substantial number of our shares of Common Stock in the public market could adversely affect the market price for our shares of Common Stock and make it more difficult for investors to sell their shares of Common Stock at times and prices that they feel are appropriate. In particular, we expect that, because there are a substantial number of shares registered pursuant to various registration statements, the applicable selling securityholders can continue to offer such covered securities for a significant period of time, the precise duration of which cannot be predicted. Accordingly, the adverse market and price pressures resulting from an offering pursuant to a registration statement or Rule 144 may continue for an extended period of time.

Sales of Common Stock pursuant to these registration statements or pursuant to Rule 144 may make it more difficult for us to sell equity securities in the future at a time and at a price that we deem appropriate. These sales also could cause the trading price of our Common Stock to fall and make it more difficult for investors to sell shares of our Common Stock at a time and price that they deem appropriate.

If securities or industry analysts either do not publish research about us or publish inaccurate or unfavorable research about us, our business, or our market, or if they change their recommendations regarding our Common Stock adversely, the trading price or trading volume of our Common Stock could decline.

The trading market for our Common Stock is influenced in part by the research and reports that securities or industry analysts may publish about us, our business, our market, or our competitors. If one or more of the analysts initiate research with an unfavorable rating or downgrade our Common Stock, provide a more favorable recommendation about our competitors, or publish inaccurate or unfavorable research about our business, the trading price of our Common Stock would likely decline. In addition, we currently expect that securities research analysts will establish and publish their own periodic projections for our business. These projections may vary widely and may not accurately predict the results we actually achieve. Our stock price may decline if our actual results do not match the projections of these securities research analysts. Furthermore, if no analysts commence coverage of our Company, the trading price and volume for our Common Stock could be adversely affected. If any analyst who may cover us were to cease coverage of the Company or fail to regularly publish reports on us, we could lose visibility in the financial markets, which in turn could cause the trading price or trading volume of our Common Stock to decline.

Delaware law and provisions in our Charter and Bylaws could make a merger, tender offer, or proxy contest difficult, thereby depressing the trading price of its Common Stock.

Our Charter and Bylaws contain provisions that could depress the trading price of our Common Stock by acting to discourage, delay, or prevent a change of control of the Company or changes in our management that our stockholders may deem advantageous. These provisions include the following:

- the right of the board of directors to establish the number of directors and fill any vacancies and newly created directorships;
- director removal solely for cause;
- "blank check" preferred stock that the Board could use to implement a stockholder rights plan;
- the right of the Board to issue our authorized but unissued Common Stock and preferred stock without stockholder approval;
- no ability of our stockholders to call special meetings of stockholders;
- no right of our stockholders to act by written consent, which requires all stockholder actions to be taken at a meeting of our stockholders;
- limitations on the liability of, and the provision of indemnification to, our director and officers;
- the right of the board of directors to make, alter, or repeal the Bylaws; and
- advance notice requirements for nominations for election to the Board or for proposing matters that can be acted upon by stockholders at annual stockholder meetings.

Any provision of the Charter or Bylaws that has the effect of delaying or deterring a change in control could limit the opportunity for our stockholders to receive a premium for their shares of our Common Stock, and could also affect the price that some investors are willing to pay for our Common Stock.

Our Bylaws provide that the Court of Chancery of the State of Delaware will be the exclusive forum for substantially all disputes between the Company and our stockholders, which could limit our stockholders' ability to obtain a favorable judicial forum for disputes with the Company or our directors, officers or employees.

The Bylaws provide that the Court of Chancery of the State of Delaware is the exclusive forum for any derivative action or proceeding brought on our behalf, any action asserting a breach of fiduciary duty, any action asserting a claim against us arising pursuant to the DGCL, the Charter or Bylaws or any action asserting a claim against us that is governed by the internal affairs doctrine. These choice of forum provisions may limit a stockholder's ability to bring a claim in a judicial forum that it finds favorable for disputes with us or our directors, officers or other employees and may discourage these types of lawsuits. This provision would not apply to claims brought to enforce a duty or liability created by the Exchange Act or any other claim for which the federal courts have exclusive jurisdiction. The Bylaws provide further that, to the fullest extent permitted by law, the federal district courts of the United States will be the exclusive forum for resolving any complaint asserting a cause of action arising under the Securities Act. However, Section 22 of the Securities Act provides that federal and state courts have concurrent jurisdiction over lawsuits brought under the Securities Act or the rules and regulations thereunder. To the extent the exclusive forum provision restricts the courts in which claims arising under the Securities Act may be brought, there is uncertainty as to whether a court would enforce such a provision. We note that investors cannot waive compliance with the federal securities laws and the rules and regulations thereunder. Furthermore, the enforceability of similar choice of forum provisions in other companies' certificates of incorporation has been challenged in legal proceedings, and it is possible that a court could find these types of provisions to be inapplicable or unenforceable. While the Delaware courts have determined that such choice of forum provisions are facially valid, a stockholder may nevertheless seek to bring a claim in a venue other than those designated in the exclusive forum provisions, and there can be no assurance that such provisions will be enforced by a court in those other jurisdictions. If a court were to find the exclusive-forum provision contained in the Bylaws to be inapplicable or unenforceable in an action, we may incur additional costs associated with resolving such action in other jurisdictions, which could harm our business.

We do not intend to pay dividends for the foreseeable future.

We currently intend to retain any future earnings to finance the operation and expansion of its business and we do not expect to declare or pay any dividends in the foreseeable future. Moreover, the terms of any revolving credit facility into which we or any of our subsidiaries enters may restrict our ability to pay dividends, and any additional debt we or any of our subsidiaries may incur in the future may include similar restrictions. As a result, stockholders must rely on sales of their Common Stock after price appreciation as the only way to realize any future gains on their investment.

We may issue additional shares of our Common Stock or other equity securities without your approval, which would dilute your ownership interests and may depress the market price of our Common Stock.

As of April 1, 2024, we have Warrants outstanding to purchase 8,528,766 shares of our Common Stock. We will also have the ability to initially issue an aggregate of 4,336,941 shares of our Common Stock under the Cardio Equity Incentive Plan, of which 3,772,425 options have been granted and are currently exercisable and 305,381 RSUs have been granted. To the extent Warrants and options are exercised, and RSUs vest, additional shares of Common Stock could be issued, which will result in dilution to our then existing stockholders and increase the number of shares eligible for resale in the public market. Sales of substantial numbers of such shares in the public market could depress the market price of our Common Stock.

At a special meeting of stockholders held on December 18, 2023, our stockholders approved the future issuance of shares of Common Stock and/or securities convertible into or exercisable for Common Stock equal to 20% or more of the Common Stock outstanding in one or more non-public transactions as required by Nasdaq Marketplace Listing Rule 5635(d) (the "Share Issuance Proposal"). Any non-public financing transaction undertaken in connection with this approval will be conducted within the parameters set forth in the Share Issuance Proposal described in the proxy statement for the Annual Meeting.

We may issue additional shares of our Common Stock or other equity securities of equal or senior rank in the future in connection with, among other things, future acquisitions or repayment of outstanding indebtedness, without stockholder approval, in a number of circumstances.

The issuance of additional shares of Common Stock or other equity securities of equal or senior rank would have the following effects:

- our existing stockholders' proportionate ownership interest in the Company will decrease;
- the amount of cash available per share, including for payment of dividends (if any) in the future, may decrease;
- the relative voting strength of each previously outstanding share of Common Stock may be diminished; and
- the market price of our shares of Common Stock may decline.

We may redeem the Public Warrants and the Sponsor Warrants prior to their exercise at a time that is disadvantageous to you, as a warrant holder, thereby making your Public Warrants or Sponsor Warrants worthless.

We have the ability to redeem outstanding Public Warrants and Sponsor Warrants at any time after they become exercisable and prior to their expiration, at a price of $0.01 per warrant, provided that the last reported sales price of our Common Stock equals or exceeds $18.00 per share (as adjusted for stock splits, stock dividends, reorganizations, recapitalizations and the like) for any 20 trading days within a 30 trading-day period ending on the third trading day prior to the date on which we give proper notice of such redemption and provided certain other conditions are met. Trading prices of our Common Stock have not historically exceeded the $18.00 per share redemption threshold. If and when the Public Warrants and Sponsor Warrants become redeemable, we may not exercise our redemption right unless there is a current registration statement in effect with respect to the shares of Common Stock underlying the Warrants. While we have registered the Common Stock issuable upon the exercise of the Public Warrants and Sponsor Warrants on a registration statement on Form S-1 that was declared effective by the SEC on January 24, 2023, it must remain current and effective by future filings. There can be no assurance that the registration statement will still be effective at the time that we would like to exercise our redemption rights.

In the event we have determined to redeem the Public Warrants and the Sponsor Warrants, holders would be notified of such redemption as described in the Warrant Agreement. Specifically, we would be required to fix a date for the redemption (the "Redemption Date"). Notice of redemption would be mailed by first class mail, postage prepaid, by the Company not less than 30 days prior to the Redemption Date to the registered holders of the Public Warrants and the Sponsor Warrants to be redeemed at their last addresses as they appear on the registration books. In addition, beneficial owners of the redeemable Public Warrants and the Sponsor Warrants will be notified of such redemption via the Company's posting of the redemption notice to DTC. Redemption of the Public Warrants and the Sponsor Warrants could force you (i) to exercise your Public Warrants and the Sponsor Warrants and pay the exercise price therefor at a time when it may be disadvantageous for you to do so, (ii) to sell your Public Warrants and the Sponsor Warrants at the then-current market price when you might otherwise wish to hold your Public Warrants and the Sponsor Warrants or (iii) to accept the nominal redemption price which, at the time the outstanding Public Warrants and the Sponsor Warrants are called for redemption, is likely to be substantially less than the market value of your Public Warrants and the Sponsor Warrants. None of the Private Placement Warrants will be redeemable.

Exercise of our Warrants is dependent upon the trading price of our Common Stock. Because of the disparity between the current stock price and the respective Warrant exercise prices, the Warrants may never be in the money and may expire worthless.

The exercise prices of our currently outstanding Warrants range from a high of $11.50 to a low of $1.78 per share. We believe the likelihood that warrant holders will exercise the Warrants, and therefore, the amount of cash proceeds that we would receive, is dependent upon the trading price of our Common Stock, the last reported sales price for which was $1.42 per share on March 28, 2024. If the trading price for our Common Stock is less than the applicable exercise price of our Warrants, we believe holders of those Warrants will be unlikely to exercise their Warrants. There is no guarantee that the Warrants will be in the money prior to their expiration, and, as such, the Warrants may expire worthless, and we may receive no proceeds from the exercise of the Warrants.

The Warrant Agreement designates the courts of the State of New York or the United States District Court for the Southern District of New York as the sole and exclusive forum for certain types of actions and proceedings that may be initiated by holders of the Warrants, which could limit the ability of warrant holders to obtain a favorable judicial forum for disputes with our Company.

The Warrant Agreement provides that, subject to applicable law, (i) any action, proceeding or claim against us arising out of or relating in any way to the Warrant Agreement, including under the Securities Act, will be brought and enforced in the courts of the State of New York or the United States District Court for the Southern District of New York, and (ii) that we irrevocably submit to such jurisdiction, which jurisdiction shall be the exclusive forum for any such action, proceeding or claim. We will waive any objection to such exclusive jurisdiction and that such courts represent an inconvenient forum. Notwithstanding the foregoing, these provisions of the Warrant Agreement will not apply to suits brought to enforce any liability or duty created by the Exchange Act or any other claim for which the federal district courts of the United States of America are the sole and exclusive forum.

Any person or entity purchasing or otherwise acquiring any interest in Warrants shall be deemed to have notice of and to have consented to the forum provisions in the Warrant Agreement. If any action, the subject matter of which is within the scope the forum provisions of the Warrant Agreement, is filed in a court other than a court of the State of New York or the United States District Court for the Southern District of New York (a "foreign action") in the name of any holder of Warrants, such holder shall be deemed to have consented to: (x) the personal jurisdiction of the state and federal courts located in the State of New York in connection with any action brought in any such court to enforce the forum provisions (an "enforcement action"), and (y) having service of process made upon such warrant holder in any such enforcement action by service upon such warrant holder's counsel in the foreign action as agent for such warrant holder.

This choice-of-forum provision may limit a warrant holder's ability to bring a claim in a judicial forum that it finds favorable for disputes with us, which may discourage such lawsuits. Alternatively, if a court were to find this provision of the Warrant Agreement inapplicable or unenforceable with respect to one or more of the specified types of actions or proceedings, we may incur additional costs associated with resolving such matters in other jurisdictions, which could materially and adversely affect our business, financial condition and results of operations and result in a diversion of the time and resources of our management and board of directors.

Financial reporting obligations of being a public company in the United States are expensive and time-consuming, and our management will be required to devote substantial time to compliance matters.

As a publicly traded company, we will incur significant additional legal, accounting and other expenses that we did not incur as a privately company. The obligations of being a public company in the United States require significant expenditures and will place significant demands on our management and other personnel, including costs resulting from public company reporting obligations under the Exchange Act and the rules and regulations regarding corporate governance practices, including those under the Sarbanes-Oxley Act of 2002 ("Sarbanes-Oxley") the Dodd-Frank Wall Street Reform and Consumer Protection Act, and the listing requirements of the stock exchange on which our securities are listed. These rules require the establishment and maintenance of effective disclosure and financial controls and procedures, internal control over financial reporting and changes in corporate governance practices, among many other complex rules that are often difficult to implement, monitor and maintain compliance with. Moreover, despite recent reforms made possible by the JOBS Act, the reporting requirements, rules, and regulations will make some activities more time-consuming and costly, particularly after we are no longer an "emerging growth company." In addition, we expect these rules and regulations to make it more difficult and more expensive for us to obtain director and officer liability insurance.

Our management and other personnel will need to devote a substantial amount of time to ensure that we comply with all of these requirements and to keep pace with new regulations, otherwise we may fall out of compliance and risk becoming subject to litigation or being delisted, among other potential problems.

If we fail to comply with the rules under Sarbanes-Oxley related to accounting controls and procedures in the future, or, if we discover material weaknesses and other deficiencies in our internal control and accounting procedures, our stock price could decline significantly and raising capital could be more difficult.

Section 404 of Sarbanes-Oxley requires annual management assessments of the effectiveness of our internal control over financial reporting. If we fail to comply with the rules under Sarbanes-Oxley related to disclosure controls and procedures in the future, or, if we discover material weaknesses and other deficiencies in our internal control and accounting procedures, our stock price could decline significantly and raising capital could be more difficult. If material weaknesses or significant deficiencies are discovered or if we otherwise fail to achieve and maintain the adequacy of our internal control, we may not be able to ensure that we can conclude on an ongoing basis that we have effective internal controls over financial reporting in accordance with Section 404 of Sarbanes-Oxley. Moreover, effective internal controls are necessary for us to produce reliable financial reports and are important to helping prevent financial fraud. If we cannot provide reliable financial reports or prevent fraud, our business and operating results could be harmed, investors could lose confidence in our reported financial information, and the trading price of our Common Stock could drop significantly.

We have incurred and will continue to incur additional costs to remediate material weaknesses in our internal control over financial reporting, as described in Item 9A. “Controls and Procedures.” The additional reporting and other obligations imposed by these rules and regulations will increase legal and financial compliance costs and the costs of related legal, accounting and administrative activities. These increased costs will require us to divert a significant amount of money that could otherwise be used to expand the business and achieve strategic objectives.

We will need to grow the size of our organization and may experience difficulties in managing this growth.

As our expansion plans and strategies develop, and as we continue to operate as a public company, we expects needing additional managerial, operational, sales, marketing, financial and other personnel. Future growth would impose significant added responsibilities on members of management, including:

- identifying, recruiting, compensating, integrating, maintaining and motivating additional employees;
- coping with demands on Management related to the increased size of its business;
- assimilating different corporate cultures and business practices;
- converting other entities’ books and records and conforming their practices to ours;
- integrating operating, accounting and information technology systems of other entities with ours and in maintaining uniform procedures, policies and standards, such as internal accounting controls; and
- improving our operational, financial and management controls, reporting systems and procedures.

Our future financial performance and our ability to expand our business will depend, in part, on our ability to effectively manage any future growth, and our management may also have to divert a disproportionate amount of its attention away from day-to-day activities in order to devote a substantial amount of time to managing these growth activities.

If we are not able to effectively expand our organization by hiring new employees and expanding our groups of consultants and contractors, we may not be able to successfully implement the tasks necessary to further develop and commercialize our product candidates and, accordingly, may not achieve our research, development and commercialization goals.

We are an “emerging growth company,” and we cannot be certain that the reduced disclosure requirements applicable to “emerging growth companies” will not make our Common Stock less attractive to investors.

We are an “emerging growth company,” as defined under the JOBS Act and will continue to be after the Business Combination is completed. For so long as we are an emerging growth company, we intend to take advantage of certain exemptions from reporting requirements that are applicable to other public companies that are not emerging growth companies, including, but not limited to, compliance with the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act, 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 stockholder approval of any golden parachute payments not previously approved.

We could be an emerging growth company for up to five years from the end of our most recently completed fiscal year, although we may lose such status earlier, depending on the occurrence of certain events, including when we have generated total annual gross revenue of at least $1.07 billion or when we are deemed to be a “large accelerated filer” under the Exchange Act, which means that the market value of our Common Stock that is held by non-affiliates exceeds $700 million as of December 31st of the prior year, or when we have issued more than $1.0 billion in nonconvertible debt securities during the prior three-year period.

We cannot predict if investors will not find our Common Stock less attractive or our company less comparable to certain other public companies because we rely on these exemptions. If some investors find our Common Stock less attractive as a result, there may be a less active trading market for our Common Stock , and our stock price may be more volatile.

Under the JOBS Act, emerging growth companies can delay adopting new or revised accounting standards issued subsequent to the enactment of the JOBS Act until such time as those standards apply to private companies. We have irrevocably elected not to avail ourselves of this exemption from new or revised accounting standards and, therefore, will be subject to the same new or revised accounting standards as other public companies that are not emerging growth companies.

As a “smaller reporting company” we are permitted to provide less disclosure than larger public companies which may make our Common Stock less attractive to investors.

We are currently a “smaller reporting company,” as defined by Rule 12b-2 of the Exchange Act. As a smaller reporting company, we are eligible to take advantage of certain exemptions from various reporting requirements applicable to other public companies. Consequently, it may be more challenging for investors to analyze our results of operations and financial prospects which may result in less investor confidence. Investors may find our Common Stock less attractive as a result of our smaller reporting company status. If some investors find our Common Stock less attractive, there may be a less active trading market for our Common Stock and our stock price may be more volatile.

There can be no assurance that we will be able to comply with the continued listing standards of Nasdaq.

Our common stock is listed on The Nasdaq Capital Market ("Nasdaq”). In order to maintain that listing, we must satisfy minimum financial and other requirements or be subject to delisting. In the second half of 2023, we received deficiency notices from Nasdaq with respect to our failure to meet the minimum bid price and the minimum stockholders’ equity requirement necessary for continued listing on Nasdaq. In both instances, we were able to cure the deficiencies within the applicable cure period, and our securities continued to trade on Nasdaq without interruption. However, there can be no assurance that we will be able to comply with the continued listing standards of Nasdaq at all times in the future. If Nasdaq delists our shares of Common Stock or Public Warrants for failure to meet the listing standards, we and our securityholders could face significant material adverse consequences including:

- a limited availability of market quotations for our securities;
- reduced liquidity for our securities;
- a determination that our common stock is a “penny stock,” which will require brokers trading in our common stock to adhere to more stringent rules, possibly resulting in a reduced level of trading activity in the secondary trading market for shares of our common stock;
- a limited amount of analyst coverage; and
- a decreased ability to issue additional securities or obtain additional financing in the future.

We may acquire other companies or technologies, which could divert our management’s attention, result in dilution to our stockholders and otherwise disrupt our operations and adversely affect our operating results.

We may in the future seek to acquire or invest in businesses, applications and services or technologies that we believe could complement or expand our services, enhance our technical capabilities or otherwise offer growth opportunities. The pursuit of potential acquisitions may divert the attention of management and cause us to incur various expenses in identifying, investigating and pursuing suitable acquisitions, whether or not they are consummated.

In addition, we do not have any experience in acquiring other businesses. If we acquire additional businesses, we may not be able to integrate the acquired personnel, operations and technologies successfully, or effectively manage the combined business following the acquisition. We also may not achieve the anticipated benefits from the acquired business due to a number of factors, including:

- inability to integrate or benefit from acquired technologies or services in a profitable manner;
- unanticipated costs or liabilities associated with the acquisition;
- difficulty integrating the accounting systems, operations, and personnel of the acquired
- difficulties and additional expenses associated with supporting legacy products and hosting infrastructure of the acquired business;
- difficulty converting the customers of the acquired business onto the Platform and contract terms, including disparities in the revenue, licensing, support, or professional services model of the acquired company;
- diversion of management's attention from other business concerns;
- adverse effects to our existing business relationships with business partners and customers as a result of the acquisition;
- the potential loss of key employees;
- use of resources that are needed in other parts of our business; and
- use of substantial portions of our available cash to consummate the acquisition.

In addition, a significant portion of the purchase price of companies we acquire may be allocated to acquired goodwill and other intangible assets, which must be assessed for impairment at least annually. In the future, if our acquisitions do not yield expected returns, we may be required to take charges to our operating results based on this impairment assessment process, which could adversely affect our results of operations.

Acquisitions could also result in dilutive issuances of equity securities or the incurrence of debt, which could adversely affect our operating results. In addition, if an acquired business fails to meet our expectations, our operating results, business and financial position may suffer.

Item 1B. Unresolved Staff Comments

Not applicable.

Item 1C. Cybersecurity

Risk Management and Strategy

We have established policies and processes for assessing, identifying, and managing material risk from cybersecurity threats, and we have integrated these processes into our overall risk management program. We assess material risks from cybersecurity threats, including any potential unauthorized occurrence on or conducted through our information systems that may result in adverse effects on the confidentiality, integrity, or availability of our information systems or any information residing therein.

We have adopted as the governance framework for our cybersecurity program the Service Organization Control Type 2 (SOC2) and the Health Insurance Portability and Accountability Act (HIPAA). We use this framework as a guide to help us identify, assess, respond to, and manage cybersecurity risks relevant to our business. Our cybersecurity risk management program includes:

• periodic risk assessments designed to help identify material cybersecurity risks to our critical systems, information, and our broader enterprise information technology environment;

• skilled information security and data privacy personnel, who support our cybersecurity risk assessment processes, our security controls, and our response to cybersecurity incidents;

• external service providers, where appropriate, to monitor, assess, test, or otherwise assist with aspects of our security controls, and to support risk mitigation efforts;

• training for our employees on cybersecurity awareness and the importance of protecting information assets.

• periodic reviews of key cybersecurity policies, and updating as needed;

• a cybersecurity incident response plan that includes procedures for responding to cybersecurity incidents.

• a third-party risk management platform is being used to govern and mitigate the potential risks, including a comprehensive process for service providers, suppliers, and vendors.

We have not identified any risks from known cybersecurity threats, including as a result of any prior cybersecurity incidents, that have materially affected or are reasonably likely to materially affect us, including our business strategy, results of operations, or financial condition.

Governance

Our Board considers cybersecurity risk as part of its risk oversight function and management expects to keep the Board informed of any material cybersecurity threats and expects to provide a report to the Board on a periodic basis and the Board will consider and oversee.

Our management team is responsible for assessing and managing our material risks from cybersecurity threats. Our Chief Technology Officer leads a team of information security professionals who have primary responsibility for our overall cybersecurity risk management program and supervises both our internal personnel and our external cybersecurity consultants.

Our management team oversees efforts to prevent, detect, mitigate, and remediate cybersecurity risks and incidents through various means, which may include threat briefings from internal personnel and external service providers, as well as alerts and reports produced by security tools deployed in the information technology environment.

Item 2. Properties

We do not own any real estate or other physical properties materially important to our operations. We currently maintain our principal executive offices at 311 W. Superior St, Ste 444, Chicago, IL 60654 pursuant to a Lease Agreement. The cost for this space is approximately $13,000 per month with an unaffiliated third party commencing on December 1, 2023 and is on a three year term. We also maintain a lab at 2565 N. Dodge, Suite D, Iowa City, IA 52245 pursuant to a Lease Agreement. The cost for this space is approximately $8,505 per month with an unaffiliated third party commencing on December 1, 2023 and is on a five year term. We consider our current office space, combined with the other office space otherwise available to our executive officers, adequate for our current operations.

Item 3. Legal Proceedings

We are not currently a party to any material litigation or other legal proceedings brought against us.

Item 4. Mine Safety Disclosures

Not applicable.

PART II

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

Market Information

Our publicly traded Common Stock and warrants are currently listed on the Nasdaq Capital Market under the symbols "CDIO" and "CDIOW," respectively.

Holders

As of April 1, 2024, there were 37 holders of record of our common stock and six holders of record of our Public Warrants and Sponsor Warrants. In addition, we have approximately 73 holders of private placement warrants, the majority of which have been registered for resale on a registration statement on Form S-1 that the SEC declared effective on January 24, 2023.

The number of record holders of our Common Stock and Public Warrants was determined from the records of our transfer agent and does not include beneficial owners of any of our securities whose securities are held in the names of various security brokers, dealers, and registered clearing agencies.

The transfer agent for our common stock and warrant agent for our warrants is Continental Stock Transfer & Trust Company.

Dividends

We have not declared or paid any cash dividends on our common stock. To date we have utilized all available cash to finance our operations. Payment of cash dividends in the future will be at the discretion of our Board of Directors and will depend upon our earnings levels, capital requirements, any restrictive loan covenants and other factors the Board considers relevant.

Warrants

As of April 1, 2024, there were 8,528,766 warrants outstanding for the purchase of Company Common Stock. Refer to Note 10 to the consolidated financial statements included in this Annual Report on Form 10-K for additional information relating to outstanding warrants.

Securities Authorized for Issuance Under Equity Compensation Plans

See Part III, Item 11, "Executive Compensation," for information about securities authorized for issuance under the Company's equity compensation plan.

Sales of Unregistered Securities

We did not sell any equity securities that were not registered under the Securities Act during the fiscal year ended December 31, 2023 that were not otherwise disclosed in our Quarterly Reports on Form 10-Q or our Current Reports on Form 8-K.

Issuer Purchases of Equity Securities

We do not currently have any plans under which the Company is able to repurchase shares of our equity securities from our stockholders.

Item 6. [Reserved]

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

As a result of the closing of the Business Combination, which was accounted for as a reverse recapitalization in accordance with U.S. GAAP as discussed in Note 2 – Merger Agreement and Reverse Recapitalization, the consolidated financial statements of Cardio Diagnostics, Inc., a Delaware corporation and our wholly owned subsidiary, are now the financial statements of the Company. You should read the following discussion and analysis of our financial condition and results of operations together with our audited consolidated financial statements as of December 31, 2023 and 2022 and for each of the two years in the period ended December 31, 2023 and the related notes included in Part II, Item 8 of this Annual Report.

Some of the information contained in this discussion and analysis or set forth elsewhere in this Annual Report, including information with respect to our plans, estimates and strategy for our business, includes forward-looking statements based upon current expectations that involve risks and uncertainties. You should read the sections titled "Risk Factors" and "Cautionary Note Regarding Forward Looking Statements" for a discussion of important factors that could cause actual results to differ materially from the results described in or implied by the forward-looking statements contained in the following discussion and analysis. Our historical results are not necessarily indicative of the results that may be expected for any period in the future.

Unless the context requires otherwise, references to "Cardio," the "Company," "we," "us" and "our" refer to Cardio Diagnostics Holdings, Inc., a Delaware corporation, together with its consolidated subsidiary.

Overview

Cardio was formed to further develop and commercialize a series of products for major types of cardiovascular disease and associated co-morbidities, including coronary heart disease ("CHD"), stroke, heart failure and diabetes, by leveraging our Artificial Intelligence ("AI")-driven Integrated Genetic-Epigenetic Engine™. As a company, we aspire to give every American adult insight into their unique risk for various cardiovascular diseases. Cardio aims to become one of the leading medical technology companies for enabling improved prevention, early detection and treatment of cardiovascular disease. Cardio is transforming the approach to cardiovascular disease from reactive to proactive and hope to accelerate the adoption of Precision Medicine for all. We believe that incorporating Cardio's solutions into routine practice in primary care and prevention efforts can help alter the trajectory that nearly one in two Americans is expected to develop some form of cardiovascular disease by 2035.

Cardio believes that it is the first company to develop and commercialize epigenetics-based clinical tests for cardiovascular disease that have clear value propositions for multiple stakeholders including (1) patients, (2) clinicians, (3) hospitals/health systems, (4) employers and (5) payors. According to the CDC, epigenetics is the study of how a person's behaviors and environment can cause changes that affect the way a person's genes work. Unlike genetic changes, epigenetic changes are reversible and do not change one's DNA sequence, but they can change how a person's body reads a DNA sequence.

Cardio launched its first clinical test, Epi+Gen CHD, in 2021 during the Covid-19 pandemic. As a result, the initial strategy for commercialization involved launching the test via telemedicine and in smaller provider practices such as concierge medicine practices. The volume of tests through these channels were minimal, and as the circumstances around Covid-19 pandemic improved, management re-vamped the Company's go-to-market strategy to include other healthcare verticals and stakeholders beyond patients and small providers, including larger provider organizations, group purchasing organizations, employers, payors and life insurers. This new approach allowed Cardio to expand the reach of our solutions beyond the initial focus areas. Despite long partnership and sales cycles, in some instance as long as 14 months, Cardio in 2023 generated revenue from patient(s), small provider(s), larger provider(s) and employer(s) and has developed a more robust sales and partnership pipeline. In addition to revenue, other key developments since our last Form 10-Q filing as of September 30, 2023, include:

- Planned launch of a new lab and fulfillment center to expand testing capacity, reduce costs, reduce turnaround time and improved margins.
- Entering into a Supply and Distribution Agreement with one of India's premier organizations, Aimil Ltd, to lay the pre-marketing groundwork via Aimil's extensive healthcare network.
- Receiving an Innovative Technology Contract from Vizient, the largest group purchasing organization with a customer base encompassing 60% of hospitals and 97% of academic medical centers in the US.
- Publication of a key peer-reviewed study on PrecisionCHD development and validation for the detection of coronary heart disease in the Journal of American Heart Association.
- An agreement with Family Medicine Specialists to test at least 1,200 of their BlueCross BlueShield and other health plan patients across four locations.
- Obtained two Current Procedural Terminology (CPT) Proprietary Laboratory Analysis (PLA) codes from the American Medical Association, 0440U for PrecisionCHD and 0439U for Epi+Gen CHD.
- The launch of HeartRisk, a cardiovascular risk intelligence platform, initially for employers to provide insights that combine HIPAA-compliant anonymized and aggregated clinical cardiovascular risk data with industry and geographic data, with the aim of helping employers understand the cardiovascular risks in their workforce compared to population and industry benchmarks.

Cardio expects that sales and partnership cycles will continue to be long. Our ongoing strategy for expanding our business operations and increasing revenue generation include the following:

- Develop additional products, including clinical tests for stroke, congestive heart failure and diabetes;
- Expand clinical and health economics evidence portfolio to continue to demonstrate value of products and increase reach;
- Leverage our newly awarded CPT PLA codes;
- Expand the adoption of our products across key channels, including health systems and self-insured employers, including for HeartRisk, Cardio's new SaaS product;
- Scale our internal operations capabilities with a focus on improving efficiency and reducing our cost of goods sold; and
- Pursue potential strategic partnership(s) and acquisition(s) of one or more synergistic companies.

Recent Developments

At the Market Sales Agreement

On January 26, 2024, the Company entered into an At-the-Market Issuance Sales Agreement (the "Sales Agreement") with Craig-Hallum Capital Group LLC ("Craig-Hallum"). Pursuant to the Sales Agreement, the Company may sell, at its option, up to an aggregate of $17 million in shares of its Common Stock through Craig-Hallum, as sales agent. Sales of the Common Stock made pursuant to the Sales Agreement have been or will be made under the Company's Registration Statement on Form S-3 filed on January 26, 2024 (File No. 333-276725) (the "Registration Statement"), which was declared effective by the Securities and Exchange Commission on February 1, 2024. Subject to the terms and conditions of the Sales Agreement, Craig-Hallum may sell the shares, if any, only by methods deemed to be an "at the market" offering as defined in Rule 415 promulgated under the Securities Act. The Company has agreed to pay Craig-Hallum a sales commission of 2.5% of the gross proceeds for sales under the Sales Agreement and to provide Craig-Hallum with customary indemnification and contribution rights, including for liabilities under the Securities Act. In addition, the Company is required to reimburse Craig-Hallum for certain specified expenses in connection with entering into the Sales Agreement.

As of April 1, 2024, the Company has sold 487,083 shares of its common stock under the Sales Agreement resulting in proceeds to the Company of $855,922, net of offering costs. The Company has paid Craig-Hallum $ 21,947 in sales commissions.

Results of Operations

The results of operations presented below should be reviewed in conjunction with the consolidated financial statements and notes included elsewhere in this Annual Report on Form 10-K. The following table sets forth Cardio's results of operations data for the periods presented:

Comparisons for the years ended December 31, 2023 and 2022:

	Years Ended December 31,	
	2023	2022
Revenue		
Revenue	$ 17,065	$ 950
Operating Expenses		
Sales and marketing	158,514	92,700
Research and development	145,182	40,448
General and administrative expenses	6,936,646	4,400,253
Amortization	19,182	16,000
Total operating expenses	(7,259,524)	(4,549,401)
Other (expense) income	(1,134,375)	(112,534)
Net (loss)	$ (8,376,834)	$ (4,660,985)

Net Loss

Cardio's net loss for the year ended December 31, 2023, was $8,376,834 as compared to $4,660,985 for the year ended December 31, 2022, an increase of $3,715,849 primarily as a result of an increase in General and Administrative expenses.

Revenue

Cardio has earned only nominal revenue since inception. Revenue for the year ended December 31, 2023, was $17,065 compared to $950 for the year ended December 31, 2022. Revenue was generated through multiple revenue channels, including, telemedicine platform, provider organizations, and employers.

Sales and Marketing

Expenses related to sales and marketing for the year ended December 31, 2023, were $158,514 as compared to $92,700 for the year ended December 31, 2022, an increase of $65,814. The overall increase was due to an increase in sales and marketing campaign efforts in 2023.

Research and Development

Research and development expense for the year ended December 31, 2023, was $145,182 as compared to $40,448 for year ended December 31, 2022, an increase of $104,734. The increase was attributable to increased laboratory runs performed in the 2023, as compared to laboratory runs performed in 2022.

General and Administrative Expenses

General and administrative expenses for the year ended December 31, 2023, were $6,936,646 as compared to $4,400,253 for the year ended December 31, 2022, an increase of $2,536,393. The overall increase is primarily due to a stock compensation of $1,035,273, an increase in rent, personnel, and office and software expenses related to new offices and the new internal lab setup.

Amortization

Amortization expense for the year ended December 31, 2023, was $19,182, as compared to $16,000 for the year ended December 31, 2022. The total amortization expense for the year ended December 31, 2023 includes the amortization of intangible assets of $16,000 and patent costs of $3,182, respectively.

Liquidity and Capital Resources

Liquidity describes the ability of a company to generate sufficient cash flows in the short- and long-term to meet the cash requirements of its business operations, including working capital needs, debt service, acquisitions and investments, and other commitments and contractual obligations. We consider liquidity in terms of cash flows from operations and other sources, and their sufficiency to fund our operating and investing activities.

Historically, our principal sources of liquidity have been proceeds from the issuance of equity and warrant exercises. More recently, upon signing the YA Securities Purchase Agreement on March 8, 2023 (the "Securities Purchase Agreement"), we issued and sold to YA II PN, Ltd. ("Yorkville") a Convertible Debenture in the principal amount of $5,000,000 for a purchase price of $4,500,000 to provide additional liquidity. Yorkville fully converted the $5,000,000 Convertible Debenture into an aggregate of 10,622,119 common shares during the year ended December 31, 2023. The Securities Purchase Agreement contemplated the issuance of a second convertible debenture in the amount of $6,200,000. However, prior to the issuance of the second convertible debenture, the Company and Yorkville terminated the Securities Purchase Agreement by the mutual consent of the parties, effective as of January 4, 2024.

On February 2, 2024, we closed a private placement with seven accredited investors, whereby we issued a total of 561,793 units ("Units"), with each Unit consisting of (i) one share of our Common Stock and (ii) one six-year Common Stock purchase warrant having an exercise price of $1.78 per share, subject to adjustment (the "Private Placement"). The Private Placement resulted in the issuance to investors of 561,793 shares of Common Stock and 561,793 warrants in an unregistered offering of securities. The purchase price of the securities was $1.78 per Unit, resulting in gross proceeds to the Company of $1,000,000, before deducting placement agent fees (10% or $100,000) and other offering expenses. We intend to use the net proceeds from the Private Placement for working capital and general corporate purposes.

As noted in Recent Developments, above, we entered into an At-the Market Sales Agreement with Craig-Hallum on January 26, 2024. As of April 1, 2024, we have received $877,869 in gross proceeds from the ATM sales, and we have available up to $16.1 million in future sales of our Common Stock that we may elect to make under the Sales Agreement.

We expect that our primary cash needs in 2024 will be for day-to-day operations, funding working capital requirements, funding our growth strategy, paying the setup expenses of our internal laboratory and paying expenses incurred in connection with our ongoing FDA submission activities. On March 22, 2023, Ladenburg, one of Mana's investment bankers, offered us a 15% early pay discount on the balance due. On March 27, 2023, we accepted Ladenburg's early pay discount offer and paid Ladenburg the net balance due and payable of $419,475. The remaining assumed liabilities balance of $435,000 was paid in full in October 2023. Accordingly, as of the date of this report, the Company has paid in full all of the liabilities it assumed in the Business Combination.

Our principal uses of cash in recent periods have been funding operations and paying expenses associated with the Business Combination. Our long-term future capital requirements will depend on many factors, including revenue growth rate, the timing and the amount of cash received from customers, the expansion of sales and marketing activities, the timing and extent of spending to support investments, including research and development efforts, and the continuing market adoption of our products. In each fiscal year since our inception, we have incurred losses from operations and generated negative cash flows from operating activities.

We continue to explore our financing options, such as equity private placement transactions. However, given recent stock prices and the extreme volatility of our stock, it continues to be challenging to balance cash that could be raised and the dilution that might be required to close a particular transaction. We expect that for the remainder of 2024, we will rely on the ongoing ATM offering, provided that market conditions are favorable.

We have had, and expect that we will continue to have, an ongoing need to raise additional cash from outside sources to fund our operations and expand our business. If we are unable to raise additional capital when desired, our business, financial condition and results of operations would be harmed. Successful transition to attaining profitable operations depends upon achieving a level of revenue adequate to support the post-merger company.

We expect that working capital requirements will continue to be funded through a combination of existing funds and further issuances of securities. Working capital requirements are expected to increase in line with the growth of the business. Existing working capital, further advances and debt instruments, and anticipated cash flow are expected to be adequate to fund operations over the next 12 months. We have no lines of credit or other bank financing arrangements. In connection with our business plan, management anticipates additional increases in operating expenses and capital expenditures relating to: (i) developmental expenses associated with a start-up business and (ii) marketing expenses. Cardio intends to finance these expenses with further issuances of securities and debt issuances. Thereafter, we expect we will need to raise additional capital and generate revenues to meet long-term operating requirements. If we raise additional funds through the issuance of equity or convertible debt securities, the percentage ownership of our equity holders could be significantly diluted, and these newly-issued securities may have rights, preferences or privileges senior to those of existing equity holders. If we raise additional funds by obtaining loans from third parties, the terms of those financing arrangements may include negative covenants or other restrictions on our business that could impair our operating flexibility and also require us to incur interest expense.

The exercise prices of our currently outstanding warrants range from a high of $11.50 to a low of $1.78 per share of Common Stock. We believe the likelihood that warrant holders will exercise their Warrants and therefore the amount of cash proceeds that we might receive, is dependent upon the trading price of our Common Stock, the last reported sales price for which was $1.42 on March 28, 2024. If the trading price of our Common Stock is less than the respective exercise prices of our outstanding Warrants, we believe holders of our Public Warrants, Sponsor Warrants and Private Placement Warrants will be unlikely to exercise their Warrants. There is no guarantee that the Warrants will be in the money prior to their respective expiration dates, and as such, the Warrants may expire worthless, and we may receive no proceeds from the exercise of Warrants. Given the current differential between the trading price of our Common Stock and the Warrant exercise prices and the volatility of our stock price, we are not making strategic business decisions based on an expectation that we will receive any cash from the exercise of Warrants. However, we will use any cash proceeds received from the exercise of Warrants for general corporate and working capital purposes, which would increase our liquidity. We will continue to evaluate the probability of Warrant exercises and the merit of including potential cash proceeds from the exercise of the Warrants in our future liquidity projections.

Cash at December 31, 2023 totaled $1,283,523 as compared to $4,117,521 at December 31, 2022, a decrease of $2,833,998. The following table shows our cash flows from operating activities, investing activities and financing activities for the stated periods:

	2023	2022
Net cash used in operating activities	$ 5,672,175	$ 5,090,968
Net cash used in investing activities	794,291	368,001
Net cash provided by financing activities	3,632,468	9,063,723

Cash Used in Operating Activities

Cash used in operating activities for the year ended December 31, 2023, was $5,672,175, as compared to $5,090,968 for the year ended December 31, 2022. The cash used in operations during the year ended December 31, 2023, is a function of net loss of $8,376,834, adjusted for the following non-cash operating items: depreciation of $3,790, amortization of $107,830, stock based compensation of $1,279,273, and non-cash interest expense of $6,704,522, offset by a change in fair value of derivative liability of $5,406,220, a gain on extinguishment of debt of $193,350, an increase in accounts receivable of $4,960, a decrease of $758,669 in prepaid expenses and other current assets, an increase in deposits of $7,900, a decrease of $781,500 in accounts payable and accrued expenses and an increase in lease liability of $244,505.

The cash used in operations during the year ended December 31, 2022, is a function of net loss of $4,660,985, adjusted for the following non-cash operating items: amortization of $16,000 and $112,534 in acquisition related expense, offset by a decrease in accounts receivable of $901, an increase of $690,821 in prepaid expenses and other current assets, an increase in deposits of $4,950 and an increase of $136,353 in accounts payable and accrued expenses.

Cash Used in Investing Activities

Cash used in investing activities for the year ended December 31, 2023, was $794,291 compared to $368,001 for the year ended December 31, 2022. The cash used in investing activities for the year ended December 31, 2023, was due to $575,663 for purchase of property and equipment, $21,352 payments for lease and $197,276 in patent and trademark costs incurred. The cash used in investing activities for the year ended December 31, 2022 was due to $4,021 cash acquired from acquisition, $137,466 repayment of deposit for acquisition, $433,334 payments for notes receivable and $76,154 in patent costs incurred.

Cash Provided by Financing Activities

Cash provided by financing activities for the year ended December 31, 2023, was $3,632,468 as compared to $9,063,723 for the year ended December 31, 2022. This change was due to $4,500,000 in proceeds from convertible note, $390,000 in proceeds from the exercise of warrants offset by $942,532 in payments pursuant to a finance agreement, and $315,000 in placement agent fees during the year ended December 31, 2023. Cash provided by financing activities for the year ended December 31, 2022 was due to $11,986,036 in proceeds from the sale of common stock, offset by $188,674 in payments of finance agreement, $1,535,035 in payments of recapitalization transaction costs and $1,198,604 in payments of placement agent fees, during the year ended December 31, 2022.

Going Concern

The accompanying consolidated financial statements have been prepared on a going concern basis, which contemplates the realization of assets and the satisfaction of liabilities in the normal course of business. The Company has generated only nominal revenue in the past two years. The Company had a net loss of $8,376,834 for the year ended December 31, 2023 and an accumulated deficit of $14,368,380 at December 31, 2023. These factors, among others, raise substantial doubt about the ability of the Company to continue as a going concern for a reasonable period of time. The Company's continuation as a going concern is dependent upon its ability to obtain necessary equity financing and ultimately from generating revenues to continue operations. The Company expects that working capital requirements will continue to be funded through a combination of its existing funds and further issuances of securities. Working capital requirements are expected to increase in line with the growth of the business. Existing working capital, further advances and debt instruments, and anticipated cash flow are expected to be adequate to fund operations over the next twelve months. The Company has no lines of credit or other bank financing arrangements. Additional issuances of equity or convertible debt securities will result in dilution to current stockholders. Further, such securities might have rights, preferences or privileges senior to common stock. Additional financing may not be available upon acceptable terms, or at all. If adequate funds are not available or are not available on acceptable terms, the Company may not be able to take advantage of prospective new business endeavors or opportunities, which could significantly and materially restrict business operations.

The consolidated financial statements do not include any adjustments that might result from the outcome of this uncertainty relating to the recoverability and classification of recorded asset amounts or the amounts and classification of liabilities that might be necessary should the Company be unable to continue as a going concern.

Off-Balance Sheet Financing Arrangements

We did not have any off-balance sheet arrangements as of December 31, 2023.

Contractual Obligations

As of December 31, 2023, we do not have any ongoing contractual obligations that would have a negative impact on liquidity and cash flows. However, if one or more of the following potential claims that arise from contracts we have entered into were pursued against us, there is the potential that we could see a negative impact on liquidity and cash flows, depending on the outcome.

Prior Relationships of Cardio with Boustead Securities, LLC

At the commencement of efforts to pursue what ultimately ended in the terminated business acquisition referred to above under "Deposit for Acquisition," Legacy Cardio entered into a Placement Agent and Advisory Services Agreement (the "Placement Agent Agreement"), dated April 12, 2021, with Boustead Securities, LLC ("Boustead Securities"). This agreement was terminated in April 2022, when Legacy Cardio terminated the underlying agreement and plan of merger and the accompanying escrow agreement relating to that proposed business acquisition after efforts to complete the transaction failed, despite several extensions of the closing deadline.

Under the terminated Placement Agent Agreement, Legacy Cardio agreed to certain future rights in favor of Boustead Securities, including (i) a two-year tail period during which Boustead Securities would be entitled to compensation if Cardio were to close on a transaction (as defined in the Placement Agent Agreement) with any party that was introduced to Legacy Cardio by Boustead Securities; and (ii) a right of first refusal to act as the Company's exclusive placement agent for 24-months from the end of the term of the Placement Agent Agreement (the "right of first refusal"). Cardio has taken the position that due to Boustead Securities' failure to perform as contemplated by the Placement Agent Agreement, these provisions purporting to provide future rights are null and void.

Boustead Securities responded to the termination of the Placement Agent Agreement by disputing Legacy Cardio's contention that it had not performed under the Placement Agent Agreement because, among other things, Boustead Securities had never sought out prospective investors. In its response, Boustead Securities included a list of funds that they had supposedly contacted on Legacy Cardio's behalf. While Boustead Securities' contention appears to contradict earlier communications from Boustead Securities in which they indicated that they had not made any such contacts or introductions, Boustead Securities is currently contending that they are due success fees for two years following the termination of the Placement Agent Agreement on any transaction with any person on the list of supposed contacts or introductions. Legacy Cardio strongly disputes this position. Notwithstanding the foregoing, the Company has not consummated any transaction, as defined, with any potential party that purportedly was a contact of Boustead Securities in connection with the Placement Agent Agreement and has no plans to do so at any time during the tail period. No legal proceedings have been instigated by either party, and Cardio believes that the final outcome will not have a material adverse impact on its financial condition.

The Benchmark Company, LLC Right of First Refusal

As noted in Note 1, the Company completed a business combination with Mana on October 25, 2022. In connection with the proposed business combination, by agreement dated May 13, 2022, Mana engaged The Benchmark Company, LLC ("Benchmark") as its M&A advisor. Upon closing of the business combination, Cardio assumed the contractual engagement entered into by Mana. On November 14, 2022, Cardio and Benchmark entered into Amendment No. 1 Engagement Letter (the "Amendment Engagement"). Pursuant to the Amendment Engagement, Benchmark has been granted a right of first refusal to act as lead or joint-lead investment banker, lead or joint-lead book-runner and/or lead or joint-lead placement agent for all future public and private equity and debt offerings through October 25, 2023. Based on the right of first refusal, Benchmark alleges that it is owed damages because the Company entered into the Yorkville Convertible Debenture Transaction (see Note 11 to Notes to Consolidated Financial Statements) without first offering Benchmark the right to serve as the lead or joint-lead placement agent for the transaction. The Company is evaluating the claim. No legal proceedings have been instigated.

Demand Letter and Potential Mootness Fee Claim

On June 25, 2022, a plaintiffs' securities law firm sent a demand letter to the Company alleging that the Company's Registration Statement on Form S-4 filed (the "S-4 Registration Statement") with the Securities and Exchange Commission ("SEC") on May 31, 2022 omitted material information with respect to the Business Combination and demanding that the Company and its Board of Directors immediately provide corrective disclosures in an amendment or supplement to the Registration Statement. Subsequent thereto, the Company filed amendments to the S-4 Registration Statement on July 27, 2022, August 23, 2022, September 15, 2022, October 4, 2022 and October 5, 2022 in which it responded to various comments of the SEC staff and otherwise updated its disclosure. In October 2022, the SEC completed its review and declared the S-4 registration statement effective on October 6, 2022. On February 23, 2023 and February 27, 2023, plaintiffs' securities law firm contacted the Company's counsel asking who will be negotiating a mootness fee relating to the purported claims set forth in the June 25, 2022 demand letter. The Company vigorously denies that the S-4 Registration Statement, as amended and declared effective, is deficient in any respect and believes that no additional supplemental disclosures are material or required. The Company believes that the claims asserted in the Demand Letter are without merit and that no further disclosure is required to supplement the S-4 Registration Statement under applicable laws. As of the date of filing of this Annual Report on Form 10-K, no lawsuit has been filed against the Company by that firm. The firm has indicated its willingness to litigate the matter if a

mutually satisfactory resolution cannot be agreed upon; however, Cardio believes that the final outcome will not have a material adverse impact on its financial condition. The Company cannot preclude the possibility that claims or lawsuits brought relating to any alleged securities law violations or breaches of fiduciary duty could potentially require significant time and resources to defend and/or settle and distract its management and board of directors from focusing on its business.

Northland Securities, Inc.

In January 2024, following the Company's termination of its agreement with Yorkville and in connection with the Company's recent at the market offering and/or its February 2024 private placement, a managing director of Northland Securities, Inc. ("Northland") contacted the Company claiming the right to be paid a fee of approximately $150,000 pursuant to the agreement of March 1, 2023 between the Company and Northland regarding the Yorkville financing. Subsequently, the Company has been advised by another representative of Northland that Northland would not proceed with any such claim. The Company does not believe that it owes Northland any sum based on the termination of the Yorkville Securities Purchase Agreement and the subsequent financing transactions.

The Company cannot preclude the possibility that claims or lawsuits brought relating to any alleged securities law violations or breaches of fiduciary duty could potentially require significant time and resources to defend and/or settle and distract its management and board of directors from focusing on its business.

Critical Accounting Policies and Significant Judgments and Estimates

Cardio's consolidated financial statements are prepared in accordance with GAAP in the United States. The preparation of its consolidated financial statements and related disclosures requires it to make estimates and judgments that affect the reported amounts of assets, liabilities, revenue, costs and expenses, and the disclosure of contingent assets and liabilities in Cardio's financial statements. Cardio bases its estimates on historical experience, known trends and events and various other factors that it believes are reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources. Cardio evaluates its estimates and assumptions on an ongoing basis. Cardio's actual results may differ from these estimates under different assumptions or conditions.

While Cardio's significant accounting policies are described in more detail in Note 3 to its consolidated financial statements, Cardio believes that the following accounting policies are those most critical to the judgments and estimates used in the preparation of its consolidated financial statements.

Principles of Consolidation

The consolidated financial statements include the accounts of the Company and its wholly owned-subsidiary, Legacy Cardio. All intercompany accounts and transactions have been eliminated.

Use of Estimates in the Preparation of Financial Statements

The preparation of financial statements in conformity with generally accepted accounting principles requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the consolidated financial statements and the reported amounts of revenues and expenses during the period. Actual results could differ from those estimates.

Fair Value Measurements

The Company adopted the provisions of ASC Topic 820, *Fair Value Measurements and Disclosures,* which defines fair value as used in numerous accounting pronouncements, establishes a framework for measuring fair value and expands disclosure of fair value measurements.

The estimated fair value of certain financial instruments, including cash and cash equivalents, accounts receivable, accounts payable and accrued expenses are carried at historical cost basis, which approximates their fair values because of the short-term nature of these instruments. The carrying amounts of our short- and long-term credit obligations approximate fair value because the effective yields on these obligations, which include contractual interest rates taken together with other features such as concurrent issuances of warrants and/or embedded conversion options, are comparable to rates of returns for instruments of similar credit risk.

ASC 820 defines fair value as the exchange price that would be received for an asset or paid to transfer a liability (an exit price) in the principal or most advantageous market for the asset or liability in an orderly transaction between market participants on the measurement date. ASC 820 also establishes a fair value hierarchy, which requires an entity to maximize the use of observable inputs and minimize the use of unobservable inputs when measuring fair value. ASC 820 describes three levels of inputs that may be used to measure fair value:

Level 1 – quoted prices in active markets for identical assets or liabilities

Level 2 – quoted prices for similar assets and liabilities in active markets or inputs that are observable

Level 3 – inputs that are unobservable (for example cash flow modeling inputs based on assumptions)

Revenue Recognition

The Company offers its products, Epi+Gen CHD and PrecisionCHD, via telemedicine providers, provider organizations such as concierge practices, longevity clinics, and risk-bearing provider organizations, and employer organizations. The Company is continuing to expand its markets and payment optionality, and therefore, other organization types not listed below may be added, and from time-to-time, there may be additional payment options.

- Telemedicine

For telemedicine, the telemedicine provider collects payments from patients upon completion of eligibility screening and test order. Patients then send their samples to the lab for biomarker assessments. The Company performs all quality control, analytical assessments and report generation and shares test reports with the ordering healthcare provider. Revenue is recognized upon invoicing the telemedicine providers. Telemedicine providers are invoiced at the end of each month for all tests completed since prior invoicing.

- Provider organizations

For provider organizations, the cost of each test is negotiated prior to testing commencing. Pricing is determined based largely on the provider organization type and testing volume commitment. Upon ordering a test, a patient's sample is sent to the lab for biomarker assessments. The Company performs all quality control, analytical assessments and report generation and shares test reports with the ordering healthcare provider. Revenue is recognized upon invoicing the provider organization. The provider organization is invoiced the agreed upon pricing at the end of each month for all samples accepted or tests completed since prior invoicing.

- Employer organizations

For employer organizations, the cost of each test is negotiated prior to testing commencing. Pricing is determined based largely on testing volume commitment. Patient samples are sent to the lab for biomarker assessments. The Company performs all quality control, analytical assessments and report generation and shares test reports with the ordering healthcare provider. Revenue is recognized upon invoicing the employer organization. The employer organization is invoiced the agreed upon pricing once a heart disease fair is completed or all testing is completed.

The Company accounts for revenue under ("ASU") 2014-09, "Revenue from Contracts with Customers (Topic 606)", using the modified retrospective method. The modified retrospective adoption used by the Company did not result in a material cumulative effect adjustment to the opening balance of accumulated deficit.

The Company determines the measurement of revenue and the timing of revenue recognition utilizing the following core principles:

1. Identifying the contract with a customer;
2. Identifying the performance obligations in the contract;
3. Determining the transaction price;
4. Allocating the transaction price to the performance obligations in the contract; and
5. Recognizing revenue when (or as) the Company satisfies its performance obligations.

Patent Costs

Cardio accounts for patents in accordance with ASC 350-30, *General Intangibles Other than Goodwill*. The Company capitalizes patent costs representing legal fees associated with filing patent applications and amortize them on a straight-line basis. The Company evaluates its patents' estimated useful life and begins amortizing the patents when they are brought to the market or otherwise commercialized.

Leases

The Company accounts for leases under ASC 842, "Leases". The Company determines if an arrangement is a lease or contains a lease at inception of the arrangement. Operating lease liabilities are recognized based on the present value of the remaining lease payments, discounted using the discount rate for the lease at the commencement date. As the rate implicit in the lease is not readily determinable for the operating lease, the Company generally uses an incremental borrowing rate based on information available at the commencement date to determine the present value of future lease payments. Operating lease right-of-use assets ("ROU assets") represent the Company's right to control the use of an identified asset for the lease term and lease liabilities represent the Company's obligation to make lease payments arising from the lease. ROU assets are generally recognized based on the amount of the initial measurement of the lease liability. Lease expense is recognized on a straight-line basis over the lease term. The Company elected to keep leases with an initial term of 12 months or less off the balance sheet.

ROU assets are reviewed for impairment when indicators of impairment are present. ROU assets from operating and finance leases are subject to the impairment guidance in ASC 360, Property, Plant, and Equipment, as ROU assets are long-lived nonfinancial assets. ROU assets are tested for impairment individually or as part of an asset group if the cash flows related to the ROU assets are not independent from the cash flows of other assets and liabilities. An asset group is the unit of accounting for long-lived assets to be held and used, which represents the lowest level for which identifiable cash flows are largely independent of the cash flows of other groups of assets and liabilities.

Stock-Based Compensation

Cardio accounts for its stock-based awards granted under its employee compensation plan in accordance with ASC Topic No. 718-20, *Awards Classified as Equity,* which requires the measurement of compensation expense for all share-based compensation granted to employees and non-employee directors at fair value on the date of grant and recognition of compensation expense over the related service period for awards expected to vest. The Company uses the Black-Scholes option pricing model to estimate the fair value of its stock options and warrants. The Black-Scholes option pricing model requires the input of highly subjective assumptions including the expected stock price volatility of the Company's common stock, the risk-free interest rate at the date of grant, the expected vesting term of the grant, expected dividends, and an assumption related to forfeitures of such grants. Changes in these subjective input assumptions can materially affect the fair value estimate of the Company's stock options and warrants.

Item 7A. Quantitative and Qualitative Disclosures About Market Risk

As of December 31, 2023, we were not subject to any market or interest rate risk.

Item 8 Financial Statements and Supplemental Data

INDEX TO FINANCIAL STATEMENTS

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Board of Directors and Stockholders of
Cardio Diagnostics Holdings, Inc.

Opinion on the Consolidated Financial Statements

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

Going Concern

The accompanying consolidated financial statements have been prepared assuming that the Company will continue as a going concern. As disclosed in Note 1 to the consolidated financial statements, the Company has generated only nominal revenue in the past two years. The Company had a net loss of $8,376,834 for the year ended December 31, 2023 and an accumulated deficit of $14,368,380 at December 31, 2023. These factors, among others, raise substantial doubt about the ability of the Company to continue as a going concern. Management's plans regarding these matters are disclosed in Note 1 to the consolidated financial statements. The consolidated financial statements do not include any adjustments that might result from the outcome of this uncertainty.

Basis for Opinion

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

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

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

/s/ Prager Metis CPA's LLC

We have served as the Company's auditor since 2021

Hackensack, New Jersey
April 1, 2024

CARDIO DIAGNOSTICS HOLDINGS, INC.
CONSOLIDATED BALANCE SHEETS
DECEMBER 31,

	2023	2022
ASSETS		
Current assets		
Cash	$ 1,283,523	$ 4,117,521
Accounts receivable	4,960	—
Prepaid expenses and other current assets	1,477,197	1,768,366
Total current assets	2,765,680	5,885,887
Long-term assets		
Property and equipment, net	571,873	—
Right of use assets, net	575,227	—
Intangible assets, net	21,333	37,333
Deposits	12,850	4,950
Patent and trademark costs, net	515,402	321,308
Total assets	$ 4,462,365	$ 6,249,478
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities		
Accounts payable and accrued expenses	$ 243,213	$ 1,098,738
Lease liability – current	223,929	—
Finance agreement payable	374,000	849,032
Total current liabilities	841,142	1,947,770
Long-term liabilities		
Lease liability – long term	663,099	—
Total liabilities	1,504,241	1,947,770
Stockholders' equity		
Preferred stock, $ .00001 par value; authorized – 100,000,000 shares; 0 shares issued and outstanding as of December 31, 2023 and 2022, respectively	—	—
Common stock, $ .00001 par value; authorized – 300,000,000 shares; 20,540,409 and 9,514,743 shares issued and outstanding as of December 31, 2023 and 2022, respectively	205	95
Additional paid-in capital	17,326,299	10,293,159
Accumulated deficit	(14,368,380)	(5,991,546)
Total stockholders' equity	2,958,124	4,301,708
Total liabilities and stockholders' equity	$ 4,462,365	$ 6,249,478

See accompanying notes to the consolidated financial statements.

CARDIO DIAGNOSTICS HOLDINGS, INC.
CONSOLIDATED STATEMENTS OF OPERATIONS
YEARS ENDED DECEMBER 31,

	2023	2022
Revenue	$ 17,065	$ 950
Operating expenses		
Sales and marketing	158,514	92,700
Research and development	145,182	40,448
General and administrative expenses	6,936,646	4,400,253
Amortization	19,182	16,000
Total operating expenses	7,259,524	4,549,401
Loss from operations	(7,242,459)	(4,548,451)

Other income (expenses)		
Change in fair value of derivative liability	5,406,220	—
Interest income	1,068	—
Interest expense	(6,735,013)	—
Gain on extinguishment of debt	193,350	—
Acquisition related expense	—	(112,534)
Total other income (expenses)	(1,134,375)	(112,534)
Loss before provision for income taxes	(8,376,834)	(4,660,985)
Provision for income taxes	—	—
Net loss	$ (8,376,834)	$ (4,660,985)
Basic and fully diluted income (loss) per common share:		
Net loss per common share	$ (.66)	$ (1.51)
Weighted average common shares outstanding – basic and fully diluted	12,685,133	3,087,683

See accompanying notes to the consolidated financial statements.

CARDIO DIAGNOSTICS HOLDINGS, INC.
CONSOLIDATED STATEMENTS OF CHANGES IN STOCKHOLDERS' EQUITY
YEARS ENDED DECEMBER 31, 2023 AND 2022

	Common stock		Additional Paid-in	Accumulated	
	Shares	Amount	Capital	Deficit	Totals
Balances, December 31, 2021	4,223,494	$ 42	$ 2,398,628	$ (1,330,561)	$ 1,068,109
Common stock and warrants issued for cash	2,484,872	25	11,986,011	—	11,986,036
Placement agent fee	—	—	(1,198,604)	—	(1,198,604)
Recapitalization transaction costs	—	—	(1,535,035)	—	(1,535,035)
Warrants converted to common stock	66,465	1	(1)	—	—
Common stock issued in merger with Mana Capital Acquisition Corp.	2,696,578	27	(27)	—	—
Note receivable converted to common stock in merger	43,334	—	(433,334)	—	(433,334)
Cash acquired in merger with Mana Capital Acquisition Corp.	—	—	4,021	—	4,021
Liabilities assumed in merger with Mana Capital Acquisition Corp.	—	—	(928,500)	—	(928,500)
Net loss	—	—	—	(4,660,985)	(4,660,985)
Balances, December 31, 2022	9,514,743	95	10,293,159	(5,991,546)	4,301,708
Warrants converted to common stock	100,000	1	389,999	—	390,000
Placement agent fee	—	—	(315,000)	—	(315,000)
Restricted stock awards vested	303,547	3	243,997	—	244,000
Notes payable converted to common stock	10,622,119	106	5,604,846	—	5,604,952
Compensation for vested stock options	—	—	1,035,273	—	1,035,273
Adjustment to liabilities assumed in merger with Mana	—	—	74,025	—	74,025
Net loss	—	—	—	(8,376,834)	(8,376,834)
Balances, December 31, 2023	20,540,409	$ 205	$ 17,326,299	$ (14,368,380)	$ 2,958,124

See accompanying notes to the consolidated financial statements.

CARDIO DIAGNOSTICS HOLDINGS, INC.
CONSOLIDATED STATEMENTS OF CASH FLOWS
YEARS ENDED DECEMBER 31,

	2023	2022
CASH FLOWS FROM OPERATING ACTIVITIES:		
Net loss	$ (8,376,834)	$ (4,660,985)
Adjustments to reconcile net loss to net cash used in operating activities		
Depreciation	3,790	—
Amortization	107,830	16,000
Acquisition related expense	—	112,534
Stock-based compensation expense	1,279,273	—
Non-cash interest expense	6,704,522	—
Change in fair value of derivative liability	(5,406,220)	—
Gain on extinguishment of debt	(193,350)	—
Changes in operating assets and liabilities:		
Accounts receivable	(4,960)	901
Prepaid expenses and other current assets	758,669	(690,821)
Deposits	(7,900)	(4,950)
Accounts payable and accrued expenses	(781,500)	136,353
Lease liability	244,505	—
NET CASH USED IN OPERATING ACTIVITIES	(5,672,175)	(5,090,968)
CASH FLOWS FROM INVESTING ACTIVITIES:		
Purchases of property and equipment	(575,663)	—
Cash acquired from acquisition	—	4,021
Repayment of deposit for acquisition	—	137,466
Payments for notes receivable	—	(433,334)
Payments for lease	(21,352)	—
Patent and trademark costs incurred	(197,276)	(76,154)
NET CASH USED IN INVESTING ACTIVITIES	(794,291)	(368,001)
CASH FLOWS FROM FINANCING ACTIVITIES:		
Proceeds from sale of common stock	—	11,986,036
Proceeds from convertible notes payable	4,500,000	—
Proceeds from exercise of warrants	390,000	—
Payments of finance agreement	(942,532)	(188,674)
Payments of recapitalization transaction costs	—	(1,535,035)
Payments of placement agent fee	(315,000)	(1,198,604)
NET CASH PROVIDED BY FINANCING ACTIVITIES	3,632,468	9,063,723
NET INCREASE (DECREASE) IN CASH	(2,833,998)	3,604,754
CASH – BEGINNING OF YEAR	4,117,521	512,767
CASH – END OF YEAR	$ 1,283,523	$ 4,117,521
SUPPLEMENTAL DISCLOSURES OF CASH FLOW INFORMATION:		
Cash paid during the year for:		
Interest	$ 30,491	$ 5,829
Income taxes	$ —	$ —
Non-cash investing and financing activities:		
Common stock issued for acquisition	$ —	$ 754
Liabilities assumed in acquisition	$ —	$ 928,500
Debt discount related to derivative liability	$ 5,000,000	$ —
Notes payable converted to common stock	$ 5,000,000	$ —
Adjustment to liabilities assumed in acquisition	$ 74,025	$ —
Financing agreement entered into for prepaid insurance	$ 467,500	$ 1,037,706
Right of use asset added for operating lease	$ 642,523	$ —

See accompanying notes to the consolidated financial statements.

CARDIO DIAGNOSTICS HOLDINGS, INC.
Notes to Consolidated Financial Statements
Years Ended December 31, 2023 and 2022

Note 1 – Organization and Basis of Presentation

The consolidated financial statements presented are those of Cardio Diagnostics Holdings, Inc., (the "Company") and its wholly-owned subsidiary, Cardio Diagnostics, Inc. ("Legacy Cardio"). The Company was incorporated as Mana Capital Acquisition Corp. ("Mana") under the laws of the state of Delaware on May 19, 2021, and Legacy Cardio was formed on January 16, 2017 as an Iowa limited liability company (Cardio Diagnostics, LLC) and was subsequently incorporated as a Delaware C-Corp on September 6, 2019. The Company was formed to develop and commercialize a patent-pending Artificial Intelligence ("AI")-driven DNA biomarker testing technology ("Core Technology") for cardiovascular disease invented at the University of Iowa by the Founders, with the goal of becoming one of the leading medical technology companies for enabling precision prevention, early detection and treatment of cardiovascular disease. The Company is transforming the approach to cardiovascular disease from reactive to proactive. The Core Technology is being incorporated into a series of products for major types of cardiovascular disease and associated co-morbidities including coronary heart disease (CHD), stroke, heart failure and diabetes.

Business Combination

On May 27, 2022, Mana, Mana Merger Sub, Inc. ("Merger Sub"), a wholly-owned direct subsidiary of Mana, Meeshanthini Dogan, the Shareholders' Representative, and Legacy

Cardio entered into the Business Combination Agreement (the "Merger Agreement"). On October 25, 2022, pursuant to the Merger Agreement, Legacy Cardio merged with and into Merger Sub, with Legacy Cardio surviving as the wholly-owned subsidiary of Mana. Subsequent to the merger, Mana changed its name to Cardio Diagnostics Holdings, Inc.

Going Concern

The accompanying consolidated financial statements have been prepared on a going concern basis, which contemplates the realization of assets and the satisfaction of liabilities in the normal course of business. The Company has generated only nominal revenue in the past two years. The Company had a net loss of $ 8,376,834 for the year ended December 31, 2023 and an accumulated deficit of $ 14,368,380 at December 31, 2023. These factors, among others, raise substantial doubt about the ability of the Company to continue as a going concern for a reasonable period of time. The Company's continuation as a going concern is dependent upon its ability to obtain necessary equity financing and ultimately from generating revenues to continue operations. The Company expects that working capital requirements will continue to be funded through a combination of its existing funds and further issuances of securities. Working capital requirements are expected to increase in line with the growth of the business. Existing working capital, further advances and debt instruments, and anticipated cash flow are expected to be adequate to fund operations over the next twelve months. The Company has no lines of credit or other bank financing arrangements. Additional issuances of equity or convertible debt securities will result in dilution to current stockholders. Further, such securities might have rights, preferences or privileges senior to common stock. Additional financing may not be available upon acceptable terms, or at all. If adequate funds are not available or are not available on acceptable terms, the Company may not be able to take advantage of prospective new business endeavors or opportunities, which could significantly and materially restrict business operations.

The consolidated financial statements do not include any adjustments that might result from the outcome of this uncertainty relating to the recoverability and classification of recorded asset amounts or the amounts and classification of liabilities that might be necessary should the Company be unable to continue as a going concern.

Note 2 – Merger Agreement and Reverse Recapitalization

As discussed in Note 1, on October 25, 2022, the Company (formerly known as Mana) and Legacy Cardio entered into the Merger Agreement, which has been accounted for as a reverse recapitalization in accordance with GAAP. Pursuant to the Merger Agreement, the Company acquired cash of $ 4,021 and assumed liabilities of $ 928,500 from Mana. The liabilities assumed of $ 928,500 are payable to two investment bankers and due on October 25, 2023. The assumed liabilities decreased to $ 854,475 , after net of an early payment discount of $ 74,025 issued by one of the two investment bankers on March 22, 2023. On March 27, 2023, the Company accepted the early payment discount and paid Ladenburg the net balance due and payable of $ 419,475 . On October 24, 2023, the Company paid the remaining post-merger liabilities balance of $ 435,000 to Benchmark.

Mana's common stock had a redemption right in connection with the business combination. Mana's stockholders exercised their right to redeem 6,465,452 shares of common stock, which constituted approximately 99.5 % of the shares with redemption rights, for cash at a redemption price of approximately $ 10.10 per share, for an aggregate redemption amount of $ 65,310,892 . In accounting for the reverse recapitalization, the Company's legacy issued and outstanding 1,976,749 shares of common stock were reversed and the Mana shares of common stock totaling 9,514,743 were recorded, as described in Note 10. Transactions costs incurred in connection with the recapitalization totaled $ 1,535,035 and were recorded as a reduction to additional paid in capital.

As additional consideration for the transaction, Cardio will issue to each holder who was entitled to merger consideration at the Closing, its *pro rata* proportion of up to 1,000,000 shares of our authorized but unissued common stock (the "Earnout Shares" or "Contingently Issuable Common Stock"), if on or prior to the fourth anniversary of the Closing Date (the "Earnout Period"), the VWAP of the Company's Common Stock equals or exceeds four different price triggers for 30 of any 40 consecutive trading days, as follows: (i) one-quarter of the Earnout Shares will be issued if the VWAP equals or exceeds $12.50 per share for the stated period; (ii) one-quarter of the Earnout Shares will be issued if the VWAP equals or exceeds $15.00 per share for the stated period; (iii) one-quarter of the Earnout Shares will be issued if the VWAP equals or exceeds $17.50 for the stated period; and (iv) one-quarter of the Earnout Shares will be issued if the VWAP equals or exceeds $20.00 for the stated period.

In evaluating the accounting treatment for the earnout, we have concluded that the earnout is not a liability under Accounting Standards Codification ("ASC") 480, Distinguishing Liabilities from Equity, is not subject to the accounting guidance under ASC 718, Compensation—Stock Compensation, and is not subject to derivative accounting under ASC 815, Derivative and Hedging. As such, the earnout is recognized in equity at fair value upon the closing of the Business Combination. As of the date of filing of this Annual Report on Form 10-K, the Company's common stock did not trade at equal to or greater than $12.50 for a period of at least 30 trading days out of 40 consecutive trading days and the Company has not issued any Earnout Shares.

Note 3 – Summary of Significant Accounting Policies

Principles of Consolidation

The consolidated financial statements include the accounts of the Company and its wholly-owned subsidiary, Legacy Cardio. All intercompany accounts and transactions have been eliminated.

Use of Estimates in the Preparation of Financial Statements

The preparation of financial statements in conformity with generally accepted accounting principles requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the consolidated financial statements and the reported amounts of revenues and expenses during the period. Actual results could differ from those estimates.

Fair Value Measurements

The Company adopted the provisions of ASC Topic 820, *Fair Value Measurements and Disclosures,* which defines fair value as used in numerous accounting pronouncements, establishes a framework for measuring fair value and expands disclosure of fair value measurements.

The estimated fair value of certain financial instruments, including cash and cash equivalents, accounts receivable, accounts payable and accrued expenses are carried at historical cost basis, which approximates their fair values because of the short-term nature of these instruments. The carrying amounts of our short- and long-term credit obligations approximate fair value because the effective yields on these obligations, which include contractual interest rates taken together with other features such as concurrent issuances of warrants and/or embedded conversion options, are comparable to rates of returns for instruments of similar credit risk.

ASC 820 defines fair value as the exchange price that would be received for an asset or paid to transfer a liability (an exit price) in the principal or most advantageous market for the asset or liability in an orderly transaction between market participants on the measurement date. ASC 820 also establishes a fair value hierarchy, which requires an entity to maximize the use of observable inputs and minimize the use of unobservable inputs when measuring fair value. ASC 820 describes three levels of inputs that may be used to measure fair value:

Level 1 – quoted prices in active markets for identical assets or liabilities

Level 2 – quoted prices for similar assets and liabilities in active markets or inputs that are observable

Level 3 – inputs that are unobservable (for example cash flow modeling inputs based on assumptions)

The estimated fair value of the derivative liability was calculated using the Black-Scholes option pricing model. The Company uses Level 3 inputs to value its derivative liabilities. The following table provides a reconciliation of the beginning and ending balances for the major classes of assets and liabilities measured at fair value using significant unobservable inputs (Level 3) and reflects gains and losses for the years ended December 31, 2023 and 2022.

	2023	2022
Liabilities:		
Balance of derivative liabilities – beginning of year	$ —	$ —
Issued	9,192,672	—
Converted	(3,786,452)	—
Change in fair value recognized in operations	(5,406,220)	—
Balance of derivative liabilities – end of year	$ —	$ —

The following table represents the Company's derivative instruments that are measured at fair value on a recurring basis as of December 31, 2023, for each fair value hierarchy level:

December 31, 2023	Derivative Liabilities	Total
Level I	$ —	$ —
Level II	$ —	$ —
Level III	$ —	$ —

Convertible Instruments

The Company evaluates and accounts for conversion options embedded in convertible instruments in accordance with ASC 815, *Derivatives and Hedging Activities.*

Applicable GAAP requires companies to bifurcate conversion options from their host instruments and account for them as free standing derivative financial instruments according to certain criteria. The criteria include circumstances in which (a) the economic characteristics and risks of the embedded derivative instrument are not clearly and closely related to the economic characteristics and risks of the host contract, (b) the hybrid instrument that embodies both the embedded derivative instrument and the host contract is not re-measured at fair value under other GAAP with changes in fair value reported in earnings as they occur and (c) a separate instrument with the same terms as the embedded derivative instrument would be considered a derivative instrument.

The Company accounts for convertible instruments (when it has been determined that the embedded conversion options should not be bifurcated from their host instruments) as follows: The Company records, when necessary, discounts to convertible notes for the intrinsic value of conversion options embedded in debt instruments based upon the differences between the fair value of the underlying common stock at the commitment date of the note transaction and the effective conversion price embedded in the note. Debt discounts under these arrangements are amortized over the term of the related debt to their stated date of redemption.

The Company accounts for the conversion of convertible debt when a conversion option has been bifurcated using the general extinguishment standards. The debt and equity linked derivatives are removed at their carrying amounts and the shares issued are measured at their then-current fair value, with any difference recorded as a gain or loss on extinguishment of the two separate accounting liabilities.

Revenue Recognition

The Company offers its products, Epi+Gen CHD and PrecisionCHD, via telemedicine providers, provider organizations such as concierge practices, longevity clinics, and risk-bearing provider organizations, and employer organizations. The Company is continuing to expand its markets and payment optionality, and therefore, other organization types not listed below may be added, and from time-to-time, there may be additional payment options.

- Telemedicine

For telemedicine, the telemedicine provider collects payments from patients upon completion of eligibility screening and test order. Patients then send their samples to the lab for biomarker assessments. The Company performs all quality control, analytical assessments and report generation and shares test reports with the ordering healthcare provider. Revenue is recognized upon invoicing the telemedicine providers. Telemedicine providers are invoiced at the end of each month for all tests completed since prior invoicing.

- Provider organizations

For provider organizations, the cost of each test is negotiated prior to testing commencing. Pricing is determined based largely on the provider organization type and testing volume commitment. Upon ordering a test, a patient's sample is sent to the lab for biomarker assessments. The Company performs all quality control, analytical assessments and report generation and shares test reports with the ordering healthcare provider. Revenue is recognized upon invoicing the provider organization. The provider organization is invoiced the agreed upon pricing at the end of each month for all samples accepted or tests completed since prior invoicing.

- Employer organizations

For employer organizations, the cost of each test is negotiated prior to testing commencing. Pricing is determined based largely on testing volume commitment. Patient samples are sent to the lab for biomarker assessments. The Company performs all quality control, analytical assessments and report generation and shares test reports with the ordering healthcare provider. Revenue is recognized upon invoicing the employer organization. The employer organization is invoiced the agreed upon pricing once a heart disease fair is completed or all testing is completed.

The Company accounts for revenue under Accounting Standards Update ("ASU") 2014-09, "Revenue from Contracts with Customers (Topic 606)", using the modified retrospective method. The modified retrospective adoption used by the Company did not result in a material cumulative effect adjustment to the opening balance of accumulated deficit.

The Company determines the measurement of revenue and the timing of revenue recognition utilizing the following core principles:

1. Identifying the contract with a customer;
2. Identifying the performance obligations in the contract;
3. Determining the transaction price;
4. Allocating the transaction price to the performance obligations in the contract; and
5. Recognizing revenue when (or as) the Company satisfies its performance obligations.

Research and Development

Research and development costs are expensed as incurred. Research and development costs charged to operations for the years ended December 31, 2023 and 2022 were $ 145,182 and $ 40,448 , respectively.

Advertising Costs

The Company expenses advertising costs as incurred. Advertising costs of $ 158,514 and $ 92,700 were charged to operations for the years ended December 31, 2023 and 2022, respectively.

Cash and Cash Equivalents

Cash and cash equivalents are comprised of cash and highly liquid investments with original maturities of 90 days or less at the date of purchase. The Company does no t have any cash equivalents as of December 31, 2023 and 2022. Cash is maintained at a major financial institution. Accounts held at U.S. financial institutions are insured by the FDIC up to $ 250,000 . The Company is exposed to credit risk in the event of default by the financial institutions or the issuers of these investments to the extent the amounts on deposit or invested are in excess of amounts that are insured.

Accounts Receivable

Accounts receivable is stated at invoiced amount, net of an allowance for doubtful accounts and bear no interest. An allowance for losses is established through a provision for losses charged to expenses. Receivables are charged against the allowance for losses when management believes collectability is unlikely. The allowance (if any) is an amount that management believes will be adequate to absorb estimated losses on existing receivables, based on evaluation of the collectability of the accounts and prior loss experience.

Property and Equipment

Property and equipment are stated at cost. Maintenance and repairs are charged to expense when incurred. When property and equipment are retired or otherwise disposed of, the related cost and accumulated depreciation are removed from the respective accounts and any gain or loss is credited or charged to income. Depreciation for both financial reporting and income tax purposes is computed using combinations of the straight line and accelerated methods over the estimated lives of the respective assets as follows:

Office and computer equipment	5 years
Furniture and fixtures	7 years

Intangible Assets

Intangible assets are acquired individually or as part of a group of assets, and are initially recorded at cost. The cost of a group of assets acquired in a transaction is allocated to the individual assets based on their relative fair values. Intangible assets are carried at cost less accumulated amortization and any recorded impairment. Intangible assets with finite useful lives are amortized using a straight-line method over the period of estimated useful life. The estimated useful life of the Company's intangible assets (Know-how license) is 5 years . The Company evaluates intangible assets for impairment whenever events or changes in circumstances indicate that the assets might be impaired.

Patent and Trademark Costs

The Company accounts for patents in accordance with ASC 350-30, the Company accounts for patents in accordance with ASC 350-30, *General Intangibles Other than Goodwill*. The Company capitalizes patent costs representing legal fees associated with filing patent applications and amortize them on a straight-line basis. The Company evaluates its patents' estimated useful life and begins amortizing the patents when they are brought to the market or otherwise commercialized.

Impairment of Long-Lived Assets

In accordance with ASC 360-10-35, the Company assesses the valuation of components of its long-lived assets whenever events or circumstances dictate that the carrying value might not be recoverable. The Company bases its evaluation on indicators such as the nature of the assets, the future economic benefit of the assets, any historical or future profitability measurements and other external market conditions or factors that may be present. If such factors indicate that the carrying amount of an asset or asset group may not be recoverable, the Company determines whether an impairment has occurred by analyzing an estimate of undiscounted future cash flows at the lowest level for which identifiable cash flows exist. If the estimate of undiscounted cash flows during the estimated useful life of the asset is less than the carrying value of the asset, the Company recognizes a loss for the difference between the carrying value of the asset and its estimated fair value, generally measured by the present value of the estimated cash flows.

Leases

The Company accounts for leases under ASC *842, "Leases".* The Company determines if an arrangement is a lease or contains a lease at inception of the arrangement. Operating lease liabilities are recognized based on the present value of the remaining lease payments, discounted using the discount rate for the lease at the commencement date. As the rate implicit in the lease is not readily determinable for the operating lease, the Company generally uses an incremental borrowing rate based on information available at the commencement date to determine the present value of future lease payments. Operating lease right-of-use assets ("ROU assets") represent the Company's right to control the use of an identified asset for the lease term and lease liabilities represent the Company's obligation to make lease payments arising from the lease. ROU assets are generally recognized based on the amount of the initial measurement of the lease liability. Lease expense is recognized on a straight-line basis over the lease term. The Company elected to keep leases with an initial term of 12 months or less off the balance sheet.

ROU assets are reviewed for impairment when indicators of impairment are present. ROU assets from operating and finance leases are subject to the impairment guidance in ASC 360, Property, Plant, and Equipment, as ROU assets are long-lived nonfinancial assets. ROU assets are tested for impairment individually or as part of an asset group if the cash flows related to the ROU assets are not independent from the cash flows of other assets and liabilities. An asset group is the unit of accounting for long-lived assets to be held and used, which represents the lowest level for which identifiable cash flows are largely independent of the cash flows of other groups of assets and liabilities.

Stock-Based Compensation

The Company accounts for its stock-based awards granted under its employee compensation plan in accordance with ASC Topic No. 718-20, Awards Classified as Equity, which requires the measurement of compensation expense for all share-based compensation granted to employees and non-employee directors at fair value on the date of grant and recognition of compensation expense over the related service period for awards expected to vest. The Company uses the Black-Scholes option pricing model to estimate the fair value of its stock options and warrants. The Black-Scholes option pricing model requires the input of highly subjective assumptions including the expected stock price volatility of the Company's common stock, the risk free interest rate at the date of grant, the expected vesting term of the grant, expected dividends, and an assumption related to forfeitures of such grants. Changes in these subjective input assumptions can materially affect the fair value estimate of the Company's stock options and warrants.

Income Taxes

The Company accounts for income taxes using the asset and liability method in accordance with ASC Topic No. 740, Income Taxes. Under this method, deferred tax assets and liabilities are determined based on differences between financial reporting and tax bases of assets and liabilities, and are measured using the enacted tax rates and laws that are expected to be in effect when the differences are expected to reverse.

The Company applies the provisions of ASC Topic No. 740 for the financial statement recognition, measurement and disclosure of uncertain tax positions recognized in the Company's financial statements. In accordance with this provision, tax positions must meet a more-likely-than-not recognition threshold and measurement attribute for the financial statement recognition and measurement of a tax position.

Recent Accounting Pronouncements

We have reviewed other recent accounting pronouncements and concluded they are either not applicable to the business, or no material effect is expected on the consolidated financial statements as a result of future adoption.

Note 4 – Property and Equipment

Property and equipment are carried at cost and consist of the following at December 31, 2023 and 2022:

	2023	2022
Office and computer equipment	$ 17,394	$ —
Furniture and fixtures	76,099	—
Leasehold improvements	482,170	—
Less: Accumulated depreciation	(3,790)	—
Total	$ 571,873	$ —

Leasehold improvements of $ 482,170 represent costs of the buildout of the leased laboratory in Iowa City, Iowa that was completed in January 2024.

Depreciation expense of $ 3,790 and $ 0 was charged to operations for the years ended December 31, 2023 and 2022, respectively.

Note 5 – Intangible Assets

The following table provides detail associated with the Company's acquired identifiable intangible assets at December 31, 2023 and 2022:

	2023	2022
Know-how license	$ 80,000	$ 80,000
Less: Accumulated amortization	(58,667)	(42,667)
Total	$ 21,333	$ 37,333

Amortization expense charged to operations was $ 16,000 for the years ended December 31, 2023 and 2022, respectively.

Note 6 – Patent and Trademark Costs

As of December 31, 2023, in the first family of patents and patent applications owned solely by UIRF and is exclusively licensed by Cardio, there are five granted patents (US, EU, China, Australia and Hong Kong) and other pending patent applications. The Company has pending patent applications in patent families two, three, four and five. Legal fees associated with the patents and trademark totaled $ 515,402 and $ 321,308 , net of accumulated amortization of $ 3,182 and $ 0 as of December 31, 2023 and 2022, respectively and are presented in the balance sheet as patent and trademark costs. Amortization expense charged to operations was $ 3,182 for the year ended December 31, 2023.

Note 7 – Operating Leases

The Company determines if a contract is, or contains, a lease at contract inception. Operating leases are included in operating lease right-of-use ("ROU") assets, current portion of operating lease liabilities and operating lease liabilities, net of current portion in the Company's consolidated balance sheets. Finance leases are included in property and equipment, current portion of finance lease obligations and finance lease obligations, net of current portion in the Company's consolidated balance sheets.

ROU assets represent the right to use an underlying asset for the lease term and lease liabilities represent the obligation to make lease payments arising from the lease. ROU assets and lease liabilities are recognized at the commencement date based on the present value of lease payments over the lease term. In addition, ROU assets include initial direct costs incurred by the lessee as well as any lease payments made at or before the commencement date and exclude lease incentives. The Company used the implicit rate in the lease in determining the present value of lease payments. Lease terms include options to extend or terminate the lease when it is reasonably certain that the Company will exercise that option. Leases with a term of one year or less are generally not included in ROU assets and corresponding operating lease liabilities.

In 2023, the Company entered into a lease agreement for office space in Chicago, Illinois, commencing on August 1, 2023 for a term of three years and four months and expiring on November 30, 2026. The monthly rent for August to November 2023 was abated and the Company started to make monthly rental installments from December 2023 of $12,847. The monthly rental payment increases by approximately 2% every August starting from 2024.

On July 20, 2023, the Company entered into another lease agreement for laboratory in Iowa City, Iowa, commencing on August 1, 2023 for a term of five years and four months and expiring on November 30, 2028. The monthly rent for August to November 2023 was abated and the Company agreed to pay a monthly rent of $ 8,505 ($ 102,060 annually) commencing December 1, 2023. In addition, the landlord agreed to provide the Company with a one-time Tenant Improvement Allowance ("TIA") in the amount of up to, but not exceeding $50 per rentable square foot of the premises for a maximum allowance of $ 253,000 .

Pursuant to ASC Topic 842 Leases, the Company accounted for both leases as operating leases and accounted for the TIA as a lease incentive, which was estimated to be payable on December 1, 2023. The Company received the TIA from landlord in maximum amount of $ 253,000 on January 16, 2024 and recorded a reimbursement receivable from landlord of $ 253,000 as of December 31, 2023, which was included in Prepaid expenses and other current assets on the consolidated balance sheets.

During the year ended December 31, 2023, the Company recorded ROU assets of $ 663,875 and operating lease liabilities of $ 642,523 at lease commencement date. The discount rate used to determine the present value is the incremental borrowing rate, estimated to be 4.57 % for Chicago lease and 4.24 % for Iowa City lease, respectively, as the interest rate implicit in our lease is not readily determinable.

As of December 31, 2023, operating lease ROU assets and operating lease liabilities are recorded on the consolidated balance sheets as follows:

	December 31, 2023
Operating Lease:	
Operating lease right-of-use assets, net	$ 575,227
Current portion of operating lease liabilities	$ 223,929
Operating lease liabilities, net of current portion	$ 663,099

As of December 31, 2023, the weighted-average remaining lease terms of the two operating leases were 2.9 years and 4.9 years, respectively.

The following table summarizes maturities of operating lease liabilities based on lease terms as of December 31:

2024	$ 257,508
2025	260,611
2026	250,152
2027	102,060
2028	93,555
Total lease payments	963,886
Less: Imputed interest	76,858
Present value of lease liabilities	$ 887,028

At December 31, 2023, the Company had the following future minimum payments due under the non-cancelable lease:

2024	$ 257,508
2025	260,611
2026	250,152
2027	102,060
2028	93,555
Total minimum lease payments	$ 963,886

Consolidated rental expense for all operating leases was $ 138,266 and $ 53,344 for the years ended December 31, 2023 and 2022, respectively.

The following table summarizes the cash paid and related right-of-use operating lease recognized for the year ended December 31, 2023.

	Year Ended December 31, 2023
Cash paid for amounts included in the measurement of lease liabilities:	
Operating cash flows from operating leases	$ 21,352
Right-of-use lease assets obtained in the exchange for lease liabilities:	
Operating leases	$ 4,950

Note 8 – Finance Agreement Payable

On October 25, 2023, the Company entered into an agreement with a premium financing company to finance its Directors and Officers insurance premiums for 12-month policies effective October 25, 2023. The amount financed of $ 467,500 is payable in 10 monthly installments plus interest at a rate of 8.95 % through August 25, 2024 . Finance agreement payable was $ 374,000 and $ 849,032 at December 31, 2023 and 2022, respectively. $ 449,041 has been recorded in prepaid expenses and is being amortized over the life of the policy.

Note 9 – Earnings (Loss) Per Common Share

The Company calculates net income (loss) per common share in accordance with ASC 260 " *Earnings Per Share*" ("ASC 260"). Basic and diluted net earnings (loss) per common share was determined by dividing net earnings (loss) applicable to common stockholders by the weighted average number of common shares outstanding during the period. The Company's potentially dilutive shares, which include outstanding common stock options, common stock warrants, and convertible debt have not been included in the computation of diluted net loss per share for the years ended December 31, 2023 and 2022 as the result would be anti-dilutive.

	Years Ended December 31,	
	2023	2022
Stock warrants	7,854,620	7,954,620
Stock options	2,584,599	1,759,599
Total shares excluded from calculation	10,439,219	9,714,219

Note 10 – Stockholders' Equity

Stock Transactions

Pursuant to the Business Combination Agreement on October 25, 2022, the Company issued the following securities:

Holders of conversion rights issued as a component of units in Mana's initial public offering (the "Public Rights") were issued an aggregate of 928,571 shares of the Company's common stock.

Holders of existing shares of common stock of Legacy Cardio and the holder of equity rights of Legacy Cardio (together, the "Legacy Cardio Stockholders") received an aggregate of 6,883,306 shares of the Company's Common Stock, calculated based on the exchange ratio of 3.427259 pursuant to the Merger Agreement (the "Exchange Ratio") for each share of Legacy Cardio Common Stock held or, in the case of the equity rights holder, that number of shares of the Company's Common Stock equal to 1% of the Aggregate Closing Merger Consideration, as defined in the Merger Agreement.

The Legacy Cardio Stockholders received, in addition, an aggregate of 43,334 shares of the Company's Common Stock ("Conversion Shares") upon conversion of an aggregate of $ 433,334 in principal amount of promissory notes issued by Mana to Legacy Cardio in connection with its loan of such amount in order to extend Mana's duration through October 26, 2022 (the "Extension Notes"), which Conversion Shares were distributed to the Legacy Cardio Stockholders in proportion to their respective interest in Legacy Cardio.

Mana public stockholders (excluding Mana Capital, LLC, the SPAC sponsor (the "Sponsor"), and Mana's former officers and directors) own 34,548 shares of the Company's Common Stock and the Sponsor, Mana's former officers and directors and certain permitted transferees own 1,625,000 shares of the Company's Common Stock.

Immediately after giving effect to the Business Combination, there were 9,514,743 issued and outstanding shares of the Company's Common Stock.

On October 25, 2022, in connection with the approval of the Business Combination, the Company's stockholders approved the Cardio Diagnostics Holdings, Inc. 2022 Equity Incentive Plan (the "2022 Plan"). The purpose of the 2022 Plan is to promote the interests of the Company and its stockholders by providing eligible employees, officers, directors and consultants with additional incentives to remain with the Company and its subsidiaries, to increase their efforts to make the Company more successful, to reward such persons by providing an opportunity to acquire shares of Common Stock on favorable terms and to attract and retain the best available personnel to participate in the ongoing business operations of the Company. The 2022 Plan permits the grant of Incentive Stock Options, Nonstatutory Stock Options, Restricted Stock, Restricted Stock Units, Stock Appreciation Rights, Performance Units and Performance Shares.

The 2022 Plan, as approved, permits the issuance of up to 3,265,516 shares of Common Stock (the "Share Reserve") upon exercise or conversion of grants and awards made from time to time to officers, directors, employees and consultants, however that the Share Reserve will increase on January 1st of each calendar year and ending on and including January 1, 2027 (each, an "Evergreen Date"), in an amount equal to the lesser of (i) 7% of the total number of shares of Common Stock outstanding on the December 31st immediately preceding the applicable Evergreen Date and (ii) such lesser number of shares of Common Stock as determined to be appropriate by the Compensation Committee, which administers the 2022 Plan, in its sole discretion. There was no increase in the Share Reserve on January 1, 2023.

Common Stock Issued

On March 2, 2023, a shareholder exercised warrants in exchange for 100,000 common shares for proceeds of $ 390,000 .

During the year ended December 31, 2023, the Company issued 52,375 common shares to a consultant for services pursuant to vesting of Restricted Stock Units granted, valued at $ 44,000 .

During the year ended December 31, 2023, the Company issued 251,172 common shares to the board of directors for services pursuant to vesting of Restricted Stock Units granted, valued at $ 200,000 .

In connection with the convertible notes payable (see Note 11 below) the noteholders converted $ 5,000,000 of principal balance to 10,622,119 shares of common stock during the year ended December 31, 2023. The number of shares of common stock issued was determined based on the terms of the convertible notes.

The Company sold post-merger 2,484,872 (or 725,032 pre-merger) common shares to various investors for proceeds totaling $ 11,986,036 during the year ended December 31, 2022. The Company paid the placement agent $ 1,198,604 in cash and issued 214,998 warrants. The Company issued post-merger 66,465 (or 19,393 pre-merger) common shares to an investor in settlement of a cashless exercise of a warrant agreement.

Warrants

On October 1, 2019, the Company issued warrants to a seed funding firm equivalent to 2% of the fully-diluted equity of the Company, or 22,500 common shares at the time of issuance. The warrant is exercisable on the earlier of the closing date of the next Qualified Equity Financing occurring after the issuance of the warrant, and immediately before a Change of Control. The exercise price is the price per share of the shares sold to investors in the next Qualified Equity Financing, or if the warrant becomes exercisable in connection with a Change in Control before the next Qualified Equity Financing, the greater of the quotient obtained by dividing $ 150,000 by the Pre-financing Capitalization, and the price per share paid by investors in the then-most recent Qualified Equity Financing, if any. The warrant will expire upon the earlier of the consummation of any Change of Control, or 15 years after the issuance of the warrant.

In April 2022, the Company issued fully vested warrants to investors as part of private placement subscription agreements pursuant to which the Company issued common stock. Each shareholder received warrants to purchase 50% of the common stock issued at an exercise price of $ 3.90 per share with an expiration date of June 30, 2027 .

As of May 23, 2022, the Company issued fully vested warrants to investors as part of an additional private placement subscription agreements pursuant to which the Company issued common stock. Each shareholder received warrants to purchase 50% of the common stock issued at an exercise price of $ 6.21 per share with an expiration date of five years from the date of issue.

All of the warrants issued by Legacy Cardio were exchanged in the Business Combination for warrants of the Company based on the merger exchange ratio.

Warrant activity during the years ended December 31, 2023 and 2022 was as follows:

	Warrant Outstanding	Weighted Average Exercise Price	Average Remaining Contractual Life (Years)
Warrants outstanding at December 31, 2021	114,924	$ 3.90	5.90
Warrants granted	1,988,973	4.84	

Warrants received in merger	5,749,993	11.50	
Merger adjustment to prior year	152,730	3.90	
Warrants exercised	(52,000)	3.90	
Warrants outstanding at December 31, 2022	7,954,620	9.63	4.72
Warrants exercised	(100,000)	3.90	
Warrants outstanding at December 31, 2023	7,854,620	$ 9.70	3.72

Options

On May 6, 2022, Legacy Cardio granted 513,413 stock options to the board of directors pursuant to the Cardio Diagnostics, Inc. 2022 Equity Incentive Plan. All of the options granted under this legacy plan were exchanged for options under the Company's 2022 Plan adopted by the Company's stockholders on October 25, 2022, and based on the exchange ratio for the merger, resulted in a total of 1,759,599 options issued upon closing. Each exchanged option has an exercise price of $ 3.90 per share with an expiration date of May 6, 2032 . The exchanged options fully vested upon closing of the merger.

Option activity during the years ended December 31, 2023 and 2022 was as follows:

	Option Outstanding	Weighted Average Exercise Price	Average Remaining Contractual Life (Years)
Options outstanding at December 31, 2021	—	$ —	
Options granted	1,759,599	3.90	
Options outstanding at December 31, 2022	1,759,599	3.90	9.35
Options granted	825,000	1.26	
Options outstanding at December 31, 2023	2,584,599	$ 3.06	8.71

Note 11 – Convertible Notes Payable

On March 8, 2023, the Company entered into a securities purchase agreement ("Securities Purchase Agreement") with YA II PN, Ltd., an investment fund managed by Yorkville Advisors Global, LP ("Yorkville") under which the Company agreed to sell and issue to Yorkville convertible debentures ("Convertible Debentures") in a gross aggregate principal amount of up to $ 11.2 million ("Subscription Amount"). The Convertible Debentures are convertible into shares of common stock of the Company and are subject to various contingencies being satisfied as set forth in the Securities Purchase Agreement. The notes are convertible at any time through the maturity date, which, in each case, is one year from the date of issuance. The conversion price shall be determined on the basis of 92 % of the two lowest VWAP (Volume Weighted Average Prices) of the Common Stock during the prior seven trading day period, initially with a floor conversion price of $ 0.55 , but subsequently lowered by mutual agreement of the parties to $ 0.20 .

On March 8, 2023, the Company issued and sold to Yorkville a Convertible Debenture in the principal amount of $ 5.0 million, for which it received $ 4.5 million, with a $ 500,000 original issue discount ("OID"). Interest on the outstanding principal balance accrues at a rate of 0 % and will increase to 15 % upon an Event of Default for so long as it remains uncured.

The Company recorded a debt discount related to identified embedded derivatives relating to the conversion features (see Note 12) based on fair values as of the inception date of the Note. The calculated debt discount, including the OID, equaled the face of the Note and is being amortized over the term of the note.

Yorkville fully converted the initial $ 5,000,000 Convertible Debenture into an aggregate of 10,622,119 common shares during the year ended December 31, 2023.

On January 4, 2024, the Company and Yorkville terminated the Securities Purchase Agreement dated as of March 8, 2023, as amended, by the mutual consent of the parties, effective as of January 4, 2024. The First Convertible Debenture has been fully converted, and as of January 4, 2024, the obligation of the Company to issue and sell, and Yorkville's obligation to purchase, the Second Convertible Debenture has been terminated. At the time of termination, there were no outstanding borrowings, advance notices or shares of Common Stock to be issued under the Securities Purchase Agreement. In addition, there were no fees due by the Company or Yorkville in connection with the termination of the Securities Purchase Agreement.

Note 12 – Derivative Liability

The Company has determined that the conversion feature embedded in the convertible notes described in Note 11 contain a potential variable conversion amount which constitutes a derivative which has been bifurcated from the note and recorded as a derivative liability at fair value, with a corresponding discount recorded to the associated debt. The excess of the derivative value over the face amount of the note is recorded immediately to interest expense at inception, which aggregated $4,692,672. The Company used the Binomial Black-Scholes Option Pricing model to value the conversion features.

The Company used Level 3 inputs for its valuation methodology for the conversion option liability in determining the fair value using a Black-Scholes option-pricing model with the following assumption inputs:

	Year Ended December 31, 2023
Annual dividend yield	—
Expected life (years)	1.0
Risk-free interest rate	4.89 % - 5.59 %
Expected volatility	164 % - 187 %
Exercise price	$ 0.19 - $ 3.53
Stock price	$ 0.22 - $ 5.32

Based upon ASC 840-15-25 (EITF Issue 00-19, paragraph 11) the Company has adopted a sequencing approach regarding the application of ASC 815-40 to its outstanding convertible notes. Pursuant to the sequencing approach, the Company evaluates its contracts based upon earliest issuance date.

Note 13 – Income Taxes

The reconciliation between income tax expense computed by applying the federal statutory corporate tax rate and actual income tax expense (benefit) for the year ended December 31, 2023 is as follows:

	Years Ended December 31, 2023	2022
Statutory U.S. federal income tax rate	(21.0)%	(21.0)%
State income taxes, net of federal income tax benefit	(0.0)%	(0.0)%
Tax effect of expenses that are not deductible for income tax purposes:		

Amortization of debt discount	16.8%	0.0%
Change in fair value of derivative liability	(13.5)%	0.0%
Other	(0.7)%	0.0%
Change in Valuation Allowance	18.4%	21.0%
Effective tax rate	0.0%	0.0%

At December 31, the significant components of the deferred tax assets (liabilities) are summarized below:

	2023	2022
Deferred Tax Assets:		
Net Operating Losses	$ 4,222,999	$ 1,611,487
Other	1,743	1,962
Stock-based compensation	486,448	186,611
Total deferred tax assets	4,711,190	1,800,060
Deferred Tax Liabilities	—	—
Valuation Allowance	(4,711,190)	(1,800,060)
Net deferred tax assets	$ —	$ —

As of December 31, 2023, the Company had federal net operating loss carryforwards of approximately $ 11.5 million which may be carried forward indefinitely, and state net operating loss carryforwards of approximately $ 11.5 million (Iowa) and $ 10.9 million (Illinois), respectively which expire at various dates from 2040 through 2043. These net operating loss carryforwards may be used to offset future taxable income and thereby reduce the Company's U.S. federal income taxes. The net operating losses may be subject to limitation under Internal Revenue Code Section 382 should there be a greater than 50 % change in ownership as determined under the regulations.

In assessing the realization of deferred tax assets, management considers whether it is more likely than not that some portion or all of the deferred tax assets will be realized. The ultimate realization of deferred tax assets is dependent upon the generation of future taxable income during the periods in which those temporary differences become deductible. Management considers the scheduled reversal of deferred tax liabilities, projected future taxable income and tax planning strategies in making this assessment. Based on the assessment, management has established a full valuation allowance against all of the deferred tax assets for every period because it is more likely than not that all of the deferred tax assets will not be realized.

In accordance with ASC 740, a valuation allowance must be established if it is more likely than not that the deferred tax assets will not be realized. This assessment is based upon consideration of available positive and negative evidence, which includes, among other things, the Company's most recent results of operations and expected future profitability. Based on the Company's cumulative losses in recent years, a full valuation allowance against the Company's deferred tax assets as of December 31, 2023 has been established as Management believes that the Company will not more likely than not realize the benefit of those deferred tax assets. Therefore, no tax provision has been recorded for the year ended December 31, 2023.

The Company complies with the provisions of ASC 740-10 in accounting for its uncertain tax positions. ASC 740-10 addresses the determination of whether tax benefits claimed or expected to be claimed on a tax return should be recorded in the financial statements. Under ASC 740-10, the Company may recognize the tax benefit from an uncertain tax position only if it is more likely that not that the tax position will be sustained on examination by the taxing authorities, based on the technical merits of the position. Management has determined that the Company has no significant uncertain tax positions requiring recognition under ASC 740-10.

The Company is subject to income tax in the U.S., and certain state jurisdictions. The Company has not been audited by the U.S. Internal Revenue Service, or any states in connection with income taxes. The Company's tax years generally remain open to examination for all federal and state income tax matters until its net operating loss carryforwards are utilized and the applicable statutes of limitation have expired. The federal and state tax authorities can generally reduce a net operating loss (but not create taxable income) for a period outside the statute of limitations in order to determine the correct amount of net operating loss which may be allowed as a deduction against income for a period within the statute of limitations.

The Company recognizes interest and penalties related to unrecognized tax benefits, if incurred, as a component of income tax expense. No interest or penalties have been recorded for the years ended December 31, 2023 and 2022, respectively.

On March 27, 2020, the Coronavirus Aid, Relief, and Economic Security Act (CARES Act) was enacted in response to the COVID-19 pandemic. The CARES Act, among other things, permits NOL carryovers and carrybacks to offset 100% of taxable income for taxable years beginning before 2021. In addition, the CARES Act allows NOLs incurred in 2018, 2019, and 2020 to be carried back to each of the five preceding taxable years to generate a refund of previously paid income taxes. The Company is currently evaluating the impact of the CARES Act, but at present does not expect that the NOL carryback provision of the CARES Act would result in a material cash benefit to us.

Note 14 – Commitments and Contingencies

Prior Relationship of Cardio with Boustead Securities, LLC

At the commencement of efforts to pursue what ultimately ended in a terminated business acquisition, Legacy Cardio entered into a Placement Agent and Advisory Services Agreement (the "Placement Agent Agreement"), dated April 12, 2021, with Boustead Securities, LLC ("Boustead Securities"). This agreement was terminated in April 2022, when Legacy Cardio terminated the underlying agreement and plan of merger and the accompanying escrow agreement relating to that proposed business acquisition after efforts to complete the transaction failed, despite several extensions of the closing deadline.

Under the terminated Placement Agent Agreement, Legacy Cardio agreed to certain future rights in favor of Boustead Securities, including (i) a two-year tail period during which Boustead Securities would be entitled to compensation if Cardio were to close on a transaction (as defined in the Placement Agent Agreement) with any party that was introduced to Legacy Cardio by Boustead Securities; and (ii) a right of first refusal to act as the Company's exclusive placement agent for 24-months from the end of the term of the Placement Agent Agreement (the "right of first refusal"). Cardio has taken the position that due to Boustead Securities' failure to perform as contemplated by the Placement Agent Agreement, these provisions purporting to provide future rights are null and void.

Boustead Securities responded to the termination of the Placement Agent Agreement by disputing Legacy Cardio's contention that it had not performed under the Placement Agent Agreement because, among other things, Boustead Securities had never sought out prospective investors. In its response, Boustead Securities included a list of funds that they had supposedly contacted on Legacy Cardio's behalf. While Boustead Securities' contention appears to contradict earlier communications from Boustead Securities in which they indicated that they had not made any such contacts or introductions, Boustead Securities is currently contending that they are due success fees for two years following the termination of the Placement Agent Agreement on any transaction with any person on the list of supposed contacts or introductions. Legacy Cardio strongly disputes this position. Notwithstanding the foregoing, the Company has not consummated any transaction, as defined, with any potential party that purportedly was a contact of Boustead Securities in connection with the Placement Agent Agreement and has no plans to do so at any time during the tail period. No legal proceedings have been instigated by either party, and Cardio believes that the final outcome will not have a material adverse impact on its financial condition.

The Benchmark Company, LLC Right of First Refusal

As noted in Note 1, the Company completed the business combination on October 25, 2022. In connection with the proposed business combination, by agreement dated May 13, 2022, Mana engaged The Benchmark Company, LLC ("Benchmark") as its M&A advisor. Upon closing of the business combination, Legacy Cardio assumed the contractual engagement entered into by Mana. On November 14, 2022, the Company and Benchmark entered into Amendment No. 1 Engagement Letter (the "Amendment Engagement"). Pursuant to the Amendment Engagement, the parties agreed that the Company would pay Benchmark $230,000 at the closing of the business combination and an additional $435,000 on October 25, 2023. Both of those payments have been made in full. In addition, the Amendment Engagement provided that Benchmark has been granted a right of first refusal to act as lead or joint-lead investment banker, lead or joint-lead book-runner and/or lead or joint-lead placement agent for all future public and private equity and debt offerings through October 25, 2023. Based on the right of first refusal, Benchmark alleges that it is owed damages because the Company entered into the Yorkville Convertible Debenture Transaction (see Note 11) without first offering Benchmark the right to serve as the lead or joint-lead placement agent for the transaction. The Company is evaluating

the claim. No legal proceedings have been instigated.

Demand Letter and Potential Mootness Fee Claim

On June 25, 2022, a plaintiffs' securities law firm sent a demand letter to the Company alleging that the Company's Registration Statement on Form S-4 filed (the "S-4 Registration Statement") with the Securities and Exchange Commission ("SEC") on May 31, 2022 omitted material information with respect to the Business Combination and demanding that the Company and its Board of Directors immediately provide corrective disclosures in an amendment or supplement to the Registration Statement. Subsequent thereto, the Company filed amendments to the S-4 Registration Statement on July 27, 2022, August 23, 2022, September 15, 2022, October 4, 2022 and October 5, 2022 in which it responded to various comments of the SEC staff and otherwise updated its disclosure. In October 2022, the SEC completed its review and declared the S-4 registration statement on October 6, 2022. On February 23, 2023 and February 27, 2023, plaintiffs' securities law firm contacted the Company's counsel asking who will be negotiating a mootness fee relating to the purported claims set forth in the June 25, 2022 demand letter. The Company vigorously denies that the S-4 Registration Statement, as amended and declared effective, is deficient in any respect and that no additional supplemental disclosures are material or required. The Company believes that the claims asserted in the Demand Letter are without merit and that no further disclosure is required to supplement the S-4 Registration Statement under applicable laws. As of the date of filing of this Annual Report on Form 10-K, no lawsuit has been filed against the Company by that firm. The firm has indicated its willingness to litigate the matter if a mutually satisfactory resolution cannot be agreed upon; however, Cardio believes that the final outcome will not have a material adverse impact on its financial condition. The Company cannot preclude the possibility that claims or lawsuits brought relating to any alleged securities law violations or breaches of fiduciary duty could potentially require significant time and resources to defend and/or settle and distract its management and board of directors from focusing on its business.

Northland Securities, Inc.

In January 2024, following the Company's termination of its agreement with Yorkville and in connection with the Company's recent at the market offering and/or its February 2024 private placement, a managing director of Northland Securities, Inc. ("Northland") contacted the Company claiming the right to be paid a fee of approximately $ 150,000 pursuant to the agreement of March 1, 2023 between the Company and Northland regarding the Yorkville financing. Subsequently, the Company has been advised by another representative of Northland that Northland would not proceed with any such claim. The Company does not believe that it owes Northland any sum based on the termination of the Yorkville Securities Purchase Agreement and the subsequent financing transactions.

The Company cannot preclude the possibility that claims or lawsuits brought relating to any alleged securities law violations or breaches of fiduciary duty could potentially require significant time and resources to defend and/or settle and distract its management and board of directors from focusing on its business.

Note 15 – Subsequent Events

The Company evaluated its December 31, 2023 consolidated financial statements for subsequent events through the date the consolidated financial statements were issued.

Common Stock Issued

Private Placement

On February 2, 2024, the Company completed entering into subscription agreements with 7 accredited investors (the "Subscription Agreements"), whereby the Company issued a total of 561,793 units ("Units"), with each Unit consisting of (i) one share of the Company's common stock, $ 0.00001 par value (the "Common Stock"), and (ii) one six year Common Stock purchase warrant (the "Warrants"), having an exercise price of $ 1.78 per share (the "Private Placement"). The Private Placement resulted in the issuance to investors of 561,793 shares of Common Stock and 561,793 Warrants. The purchase price of the securities was $ 1.78 per Unit, resulting in gross proceeds to the Company of $ 1,000,000 and paid a fee of $ 100,000 , before deducting placement agent fees (10% or $ 100,000) and other offering expenses. The Company intends to use the net proceeds from the Private Placement for working capital and general corporate purposes. The Private Placement closed on February 2, 2024.

In connection with the Private Placement, the Company entered into a Placement Agent Agreement with Altitude Capital Group, LLC, as placement agent ("Altitude Capital" or the "Placement Agent"). Pursuant to the Placement Agent Agreement, at closing, Altitude Capital was paid a cash commission equal to 10% of the gross proceeds received by the Company, plus 20% warrant coverage, providing Altitude Capital with the right to purchase 112,353 shares of Common Stock at $ 1.78 per share through February 2, 2030 (the "Placement Agent Warrants").

At-the-Market Issuance

On January 26, 2024, the Company entered into an At-the-Market Issuance Sales Agreement (the "Sales Agreement") with Craig-Hallum Capital Group LLC ("Craig-Hallum"). Pursuant to the Sales Agreement, the Company may sell, at its option, up to an aggregate of $ 17 million in shares of its common stock through Craig-Hallum, as sales agent. Sales of the common stock made pursuant to the Sales Agreement, if any, will be made under the Company's Registration Statement on Form S-3 filed on January 26, 2024 (File No. 333-276725) (the "Registration Statement"), which was declared effective by the Securities and Exchange Commission on February 1, 2024.

The Company made certain customary representations, warranties and covenants concerning the Company and the offering of the Shares. Pursuant to the terms of the Sales Agreement, the Company also provided the Sales Agent with customary indemnification rights, including indemnification against certain liabilities under the Securities Act. The Company will pay the Sales Agent a commission in cash equal to 2.5% of the gross proceeds from the sale of the Shares under the Sales Agreement, if any. In addition, the Company agreed to pay the costs of the Sales Agent's legal counsel reasonably incurred in connection with entering into the transactions contemplated by the Sales Agreement in an amount not to exceed $55,000. Additionally, pursuant to the terms of the Sales Agreement, the Company agreed to reimburse the Sales Agent's for its legal fees incurred in connection with its ongoing diligence requirements arising from the transactions contemplated by the Sales Agreement in an amount not to exceed $5,000 in the aggregate per calendar quarter. The offering of Shares will terminate upon the earlier of (i) the sale of the Shares under the Sales Agreement having an aggregate offering price of $17 million or (ii) the termination of the Sales Agreement as permitted therein. The Sales Agreement may be terminated by the Company at any time upon five business days' prior written notice to the Sales Agent. The Sales Agent may terminate the Sales Agreement at any time by providing written notice to the Company. The Company and the Sales Agent may also terminate the Sales Agreement by mutual agreement.

The Company sold 487,083 common shares for gross proceeds totaling $ 877,869 under the Sales Agreement as of the date of this report. The Company has paid Craig-Hallum $ 21,947 in sales commissions.

Stock Option Granted

On January 23, 2024, the Company authorized an additional 1,071,425 shares to the Equity Incentive Plan Reserve (the "2022 Plan") and granted 1,187,826 options to management, 1,166,826 of which vested immediately with the remaining 21,000 options subject to 50 % vesting on June 30, 2024 and 100 % vesting on December 31, 2024. Each option has an exercise price of $ 2.11 per share with an expiration date of January 23, 2034 .

Item 9. Changes in and Disagreements with Accountants on Accounting and Financial Disclosure

None.

Item 9A. Controls and Procedures Evaluation of Disclosure Controls and Procedures

Evaluation of Disclosure Controls and Procedures

Under the supervision and with the participation of our management, including our principal executive officer and principal financial and accounting officer, we conducted an evaluation of the effectiveness of our disclosure controls and procedures as of December 31, 2023, as such term is defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act. Based on this evaluation, our principal executive officer and principal financial and accounting officer have concluded that during the period covered by this report, our disclosure controls and procedures were not effective. As a result, we performed additional analysis as deemed necessary to ensure that our financial statements were prepared in accordance with U.S. generally accepted accounting principles. Accordingly, management believes that the financial statements included in this Form 10-K present fairly in all material respects our financial position, results of operations and cash flows for the period presented.

Disclosure controls and procedures are designed to ensure that information required to be disclosed by us in our Exchange Act reports is recorded, processed, summarized, and reported within the time periods specified in the SEC's rules and forms, and that such information is accumulated and communicated to our management, including our principal executive officer and principal financial officer or persons performing similar functions, as appropriate to allow timely decisions regarding required disclosure.

We do not expect that our disclosure controls and procedures will prevent all errors and all instances of fraud. Disclosure controls and procedures, no matter how well conceived and operated, can provide only reasonable, not absolute, assurance that the objectives of the disclosure controls and procedures are met. Further, the design of disclosure controls and procedures must reflect the fact that there are resource constraints, and the benefits must be considered relative to their costs. Because of the inherent limitations in all disclosure controls and procedures, no evaluation of disclosure controls and procedures can provide absolute assurance that we have detected all our control deficiencies and instances of fraud, if any. The design of disclosure controls and procedures also is based partly on certain assumptions about the likelihood of future events, and there can be no assurance that any design will succeed in achieving its stated goals under all potential future conditions.

Management's Report on Internal Controls Over Financial Reporting

This Annual Report on Form 10-K does not include a report of management's assessment regarding internal control over financial reporting or an attestation report of our independent registered public accounting firm due to a transition period established by rules of the SEC for newly public companies.

Changes in Internal Control over Financial Reporting

There have been no changes in our internal control over financial reporting during the period ended December 31, 2023 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

Item 9B. Other Information

During the Company's fourth quarter, no director or officer adopted or terminated a Rule 10b5-1 trading arrangement or a non-Rule 10b5-1 trading arrangement.

Item 9C. Disclosure Regarding Foreign Jurisdictions that Prevent Inspections

Not applicable.

PART III

Item 10. Directors, Executive Officers and Corporate Governance.

The following table sets forth certain information, including ages as of April 1, 2024, of our executive officers and members of the Board of Directors.

Name	Age	Position
Executive Officers		
Meeshanthini (Meesha) V. Dogan, PhD	35	Chief Executive Officer and Director
Robert (Rob) Philibert, MD PhD	62	Chief Medical Officer and Director
Elisa Luqman, JD MBA	59	Chief Financial Officer
Timur Dogan, PhD	36	Chief Technology Officer
Khullani Abdullah, JD	40	Vice President of Revenue and Strategy
Non-Employee Directors		
Warren Hosseinion, MD	52	Non-Executive Chairman
James Intrater	60	Director
Stanley K. Lau, MD	68	Director
Oded Levy	65	Director
Paul Burton	56	Director

Biographical Information

Executive Officers

The following is a brief biography of each of our executive officers:

Meeshanthini V. Dogan has served as our Chief Executive Officer and a director since inception. Together with Dr. Philibert, she is the Co-Founder of Legacy Cardio, with over 13 years' experience in bridging medicine, engineering and artificial intelligence towards building solutions to fulfill unmet clinical needs such as in cardiovascular disease prevention and management. Coming from a family with a two-generation history of heart disease and having worked for an extensive time interacting with those affected by heart disease, she understands the pain points and founded Legacy Cardio to help prevent others from experiencing its devastating impacts. Dr. Dogan is a pioneer in artificial intelligence/machine learning-driven integrated genetic-epigenetic approaches, which includes highly cited publications, and platform presentations at the American Heart Association and American Society of Human Genetics. She co-invented the patent-pending Integrated Genetic-Epigenetic Engine™ of Cardio Diagnostics (six granted patents and numerous pending patents). In 2017, Dr. Dogan founded Legacy Cardio to commercialize this technology through a series of patent-pending clinical tests towards making heart disease prevention and early detection more accessible, personalized and precise. Under her leadership, Legacy Cardio was awarded the prestigious One To Watch award in 2020 by Nature and Merck, the 2021 Clinical Diagnostics Solution of the Year from Biotech Breakthrough and Fast Company's Next Big Things in Tech 2022, has worked its way to become a technology leader in cardiovascular diagnostics, launched four products, secured both dilutive and non-dilutive funding and key relationships with world renowned healthcare organizations and key opinion leaders. Dr. Dogan holds a PhD degree in Biomedical Engineering and BSE/MS degrees in Chemical Engineering from University of Iowa. She was named FLIK Woman Entrepreneur to Watch in 2021. We believe that, as a co-founder of our Company and co-inventor of our Company's key technologies and products, as well as her leadership skills, Dr. Dogan is uniquely positioned to bring unmatched experience and insights into the boardroom and to the daily operations of our Company.

Robert Philibert has served as our Chief Medical Officer and as a director since inception. Together with Dr. Dogan, he is a co-founder of Legacy Cardio. Dr. Philibert graduated from the University of Iowa Medical Scientist Training Program and completed a residency in Psychiatry at the University of Iowa. Between 1993 and 1998, he completed a Pharmacology Research Training Program ("PRAT") Fellowship and a Staff Fellowship at the National Institutes of Health while also serving in the United States Uniformed Public Health Service. In late 1998, he returned to the University of Iowa where he now is a Professor of Psychiatry, with joint appointments in Neuroscience, Molecular Medicine and Biomedical Engineering. He has published over 170 peer reviewed manuscripts and is the recipient of numerous NIH grant awards and both national and international patents for his pioneering work in epigenetics. In particular, he is credited with discovering the epigenetic signatures for cigarette and alcohol consumption. In 2009, he founded Behavioral Diagnostics, LLC, a leading provider of epigenetic testing services which has introduced two epigenetic tests, Smoke Signature© and Alcohol Signature™ to the commercial market. Simultaneously, he has licensed related non-core technologies to manufacturing partners while developing an ecosystem of key complementary service providers in the clinical diagnostics space.

Elisa Luqman has served as our Chief Financial Officer on a part time basis since March 2021. In March 2021, Legacy Cardio and Ms. Luqman entered into a consulting agreement under which she was retained to provide services in connection with a potential merger transaction. Since April 2022, Ms. Luqman has also been serving as Chief Legal Officer (SEC) for Nutex Health, Inc. ("Nutex"), a physician-led, technology-enabled healthcare services company. She attained that position upon the closing of a merger transaction in which her employer, Clinigence Holdings, Inc. ("Clinigence"), was the surviving entity. She served as the Chief Financial Officer, Executive Vice President Finance and General Counsel of Clinigence from October 2019 until the merger. She also served as a director of Clinigence from October 2019 to February 2021. At Clinigence, Ms. Luqman was responsible for maintaining the corporation's accounting records and statements, preparing its SEC filings and overseeing compliance requirements. She was an integral member of the Clinigence team responsible for obtaining the company's NASDAQ listing and completing the reverse merger with Nutex. At Nutex Ms. Luqman continues to be responsible for preparing its SEC filings and overseeing compliance requirements. Ms. Luqman co-founded bigVault Storage Technologies, a cloud- based file hosting company acquired by Digi-Data Corporation in February 2006. From March 2006 through February 2009, Ms. Luqman was employed as Chief Operating Officer of the Vault Services Division of Digi-Data Corporation, and subsequently during her tenure with Digi-Data Corporation she became General Counsel for the entire corporation. In that capacity

she was responsible for acquisitions, mergers, patents, customer, supplier, and employee contracts, and worked very closely with Digi-Data's outside counsel firms. In March 2009, Ms. Luqman rejoined iGambit Inc. ("IGMB") as Chief Financial Officer and General Counsel. Ms. Luqman has overseen and been responsible for IGMB's SEC filings, FINRA filings and public company compliance requirements from its initial Form 10 filing with the SEC in 2010 through its reverse merger with Clinigence Holdings, Inc. in October 2019. Ms. Luqman received a BA degree, a JD in Law, and an MBA Degree in Finance from Hofstra University. Ms. Luqman is a member of the bar in New York and New Jersey.

Timur Dogan has served as our Chief Technology Officer since May 2022. He has been employed by Legacy Cardio since August 2019, after obtaining his Ph.D., and was serving as its Senior Data Scientist until he was promoted to CTO. Dr. Dogan was instrumental in developing and advancing the Integrated Genetic-Epigenetic Engine™ that is at the core of Cardio's cardiovascular solutions. Along with the founding team, he is the co-inventor of two patent-pending technologies in cardiovascular disease and diabetes. He holds a joint B.S.E./M.S. and Ph.D. degrees in Mechanical Engineering from the University of Iowa where he researched complex fluid flows. He developed machine learning models on high-performance computing systems using a mixture of low and high-fidelity numerical simulations and experiments to draw insights from non-linear physics.

Khullani Abdullahi has served as our Vice President of Revenue and Strategy since May 2022. In July 2020, Ms. Abdullahi began working with Legacy Cardio as a consultant, where she was a member of the advisory board as a go-to-market and growth advisor and provided other services as mutually agreed upon. After two years as an advisor, in May 2022, she joined Cardio full-time to lead the sales, marketing, and customer success teams. Ms. Abdullahi has more than ten years of experience as a revenue and sales strategist, helping clients and companies develop and execute aggressive customer-acquisition campaigns, services she provides to various clients through Episteme X, her consulting company. She has led commercialization, pricing, and monetization strategies and scaled revenue teams in healthcare and biotech. As a data-driven account-based marketing revenue strategist, her methods emphasize identifying all relevant contacts across the total addressable target market to drive defensive market penetration growth. Ms. Abdullahi holds a BA in Philosophy from Carleton College and a Juris Doctor from the University of Minnesota Law School.

Non-Employee Members of the Board of Directors

The following is a brief biography of each of our non-employee directors:

Warren Hosseinion, MD has served as the Company's Non-Executive Chairman of the Board since the consummation of the Business Combination in October 2022. He was Legacy Cardio's Non-Executive Chairman of the Board from May 2022 and was on Legacy Cardio's Board of Directors beginning in November 2020. In March 2021, Legacy Cardio and Dr. Hosseinion entered into a consulting agreement under which he was retained to provide services in connection with a potential merger transaction. He continues to provide consulting services to the Company under that contract. He is also currently the President and a director of Nutex Health, Inc. (Nasdaq: NUTX), positions he has held since April 2022. In 2001, Dr. Hosseinion co-founded Astrana Health, Inc. (Nasdaq: ASTH) (formerly, Apollo Medical Holdings, Inc. (Nasdaq: AMEH)) and has served as a member of Astrana's Board of Directors since July 2008. He served as Astrana's Chief Executive Officer from July 2008 to December 2017 and its Co-Chief Executive Officer from December 2017 to March 2019. Dr. Hosseinion received his B.S. in Biology from the University of San Francisco, his M.S. in Physiology and Biophysics from the Georgetown University Graduate School of Arts and Sciences, his Medical Degree from the Georgetown University School of Medicine and completed his residency in internal medicine from the Los Angeles County-University of Southern California Medical Center. Dr. Hosseinion's experience as a physician, along with his background at Astrana and Nutex, brings our Board and our Company a depth of understanding of physician culture and the healthcare market, as well as a strong knowledge of the public markets.

James Intrater is the director who was designated by Mana, and he began his term upon Closing of the Business Combination in October 2022 . Mr. Intrater is a senior materials and process engineer with over 35 years of professional experience. He has worked in both commercial product development and on Federal R&D projects, including work for NASA, the U.S. Department of Defense, and the U.S. Department of Energy. Since June 2014, Mr. Intrater has served as the president of IntraMont Technologies, a consumer health products development company. In addition, since May 2020, he has also provided engineering consultancy services for Falcon AI, a private investment firm to evaluate potential portfolio investments. Mr. Intrater has published numerous technical works and reports for various agencies of the federal government and in technical journals and is listed as holder or co-holder of five patents, with another patent pending. Mr. Intrater received his Master of Science in Metallurgical Engineering from the University of Tennessee and a Bachelor of Sciences in Ceramic Engineering from Rutgers University - College of Engineering. Mr. Intrater was selected to serve as a member of our board of directors due to his significant experience developing healthcare-related products as well as products in other industries.

Stanley K. Lau, MD has served as a member of the Company's Board of Directors since consummation of the Business Combination in October 2022 . In September 2006, Dr. Lau founded Synergy Imaging Center, San Gabriel, California, where he has held the position of Medical Director since inception. In addition, since November 1997, Dr. Lau has been affiliated with the Southern California Heart Centers, San Gabriel, California, which he founded. Earlier in his professional career, from November 1996 to November 1997, Dr. Lau served as an Assistant Professor in Cardiology at Texas Tech University, and from August 1995 to November 1996, he provided cardiovascular consulting services at Chandra Cardiovascular Consultant, PC, Sioux City, Iowa. Dr. Lau has the following clinical appointments at the Garfield Medical Center, Monterey Park, California: Director, Cardiac Structural Heart Program, Chairman of the Cardiovascular Committee, member of the Board of Directors, Los Angeles County certified ST-Elevation Myocardial Infarction (STEM) Program Director and Director of the Cardiac Catheterization Lab. Dr. Lau received his M.B.B.S (Bachelor of Medicine and Bachelor of Surgery) in 1984 from the University of New South Wales School of Medicine, Sydney, Australia. He received further training at the University of Southern California, specializing in diagnostic cardiac catheterization, coronary angioplasty, coronary artery stenting, intervascular ultrasound, renal and peripheral diagnostic angiograms and pacemaker implantation. He is board certified in interventional cardiology, cardiovascular disease, internal medicine, certification board of cardiovascular computer tomography, echocardiography subspecialty, acute critical care echocardiography subspecialty, nuclear cardiology subspecialty and is board certified as a hypertension specialist. He also extensive experience in coronary CT Angiogram and Cardiac MRI. He has a level III (highest) Certification in CCTA by the Society of Cardiovascular Computed Tomography and a Level II Certification in Cardiac MR by the Society of Cardiovascular Magnetic Resonance, in addition to being board certified in Cardiovascular Disease, Internal Medicine, Echocardiography, Nuclear Cardiology and as a Hypertension Specialist. Dr. Lau also founded the structured heart program at Garfield Medical Center, recently implementing the TAVR program in 2017. Dr. Lau received his medical degree from the University of New South Wales School of Medicine in Sydney, Australia, and completed his Residency in Internal Medicine, Fellowship in Cardiology and Fellowship in Interventional Cardiology at the University of Southern California. Dr. Lau was selected to serve on our board of directors due to his extensive academic and clinical experience in internal medicine and cardiology.

Oded Levy has served as a member of the Company's Board of Directors since consummation of the Business Combination in October 2022. He is the founder, president and managing partner of Blue Ox Healthcare Partners, ("Blue Ox") a private equity firm based in New York City that invests growth capital in commercial-stage healthcare companies, with a focus on companies involved in precision health. Mr. Levy has over 30 years of experience in specialized healthcare investing in private equity, capital markets and asset management. He co-founded Blue Ox in 2009, leads origination and structuring of the firm's investments, and chairs the Investment Committee. Prior to Blue Ox, he was a principal at Oracle Partners, LP, a private investment firm specializing in public securities investing and merchant banking in the healthcare, bioscience and related industries. Previously, he was Head Trader and a member of the Executive Committee at Genesis Merchant Group Securities ("GMGS"), a San Francisco-based investment bank. Mr. Levy was also Senior Vice President of Investments at Bering Holdings, Inc., the investment arm of publicly traded MAXXAM, Inc. He began his career in 1987 as a corporate finance analyst at Bear, Stearns & Co. Inc. Mr. Levy previously served on the boards of former Blue Ox investments, MedSave USA, as Executive Chairman, Delphi Behavioral Health Group and Infinity Funding. He holds an MBA in Finance and International Business and a BS in Computer and Information Systems from New York University. Mr. Levy was selected to serve on the board of directors due to his significant experience managing and investing in healthcare companies.

Paul F. Burton has served as a member of the Company's Board of Directors since December 2023. Since May 2021, Mr. Burton has served as the Managing Partner, of 2Flo Ventures, a start-up studio and early-stage healthcare investor. Through 2Flo Ventures, he provides strategic and financial advice to healthcare companies. In 2010, he founded and continues to serve as Managing Principal of Burton Advisory, Inc., which provides strategic and financial advice to healthcare companies, drawing from over 20 years of experience in corporate finance and strategic advisory services. In connection therewith, since December 2018, Mr. Burton has been the Chief Executive Officer of Akan Biosciences, a biotech start-up company developing regenerative medicinal therapeutics. From 2019 he also has been serving as the Chief Financial Officer of Temprian Therapeutics. From 2019 through 2022 he served as the fractional CFO for both Cancer IQ and 4D Healthware. From 2019 through 2022, Mr. Burton was also an Entrepreneur in Residence at Northwestern University, supporting students and faculty with healthcare-oriented commercialization projects. Previously, he was the Chief Executive Officer of ResQ Pharma, Inc. In 2013 he co-founded Vivacelle Bio, Inc., where he served as Chief Financial Officer and a member of its board of directors. Mr. Burton currently serves as a member of the Chicago Biomedical Consortium's VC Advisory Committee, as a member of MATTER, a Chicago-based healthcare incubator, and the Bunker Labs, an incubator started in Chicago for U.S. military veterans. He also is a member of the Board of Directors of Millennium Beacon, a healthcare incubator based on the southside of Chicago, seeking to serve overlooked populations. Prior thereto, Mr. Burton worked as an investment banking associate at Salomon Brothers (now Citigroup Corporate & Investment Bank). He also served as a United States Regular Army Commissioned Officer (Infantry). Mr. Burton earned his JD and MBA from the University of Illinois at Urbana-Champaign and earned two Bachelor's Degrees from the University of Illinois at Chicago. He currently serves on the Board of Trustees of the Ravinia Festival, an internationally-renowned, not-for-profit music festival. Mr. Burton was nominated due to his extensive experience in the working of numerous capacities with early-stage healthcare companies as well as his corporate finance background, both of which are areas of expertise we believe will bring invaluable insights to the Cardio boardroom.

Family Relationships

Other than Meeshanthini Dogan and Timur Dogan, who are wife and husband, t here are no family relationships among our executive officers and directors.

Corporate Governance

Cardio has structured its corporate governance in a manner that we believe closely aligns its interests with those of its stockholders. Notable features of this corporate governance include:

- Cardio has independent director representation on its audit, compensation and nominating and corporate governance committees, and its independent directors will meet regularly in executive sessions without the presence of its corporate officers or non-independent directors;
- at least one of its directors has qualified as an "audit committee financial expert" as defined by the SEC; and
- it has and will implement a range of other corporate governance best practices.

Composition of the Board of Directors and Company Officers

Cardio's business and affairs are managed under the direction of our board of directors.

The Company's board consists of seven directors. The board of directors are elected each year at the annual meeting of stockholders.

The Company officers are appointed by the board of directors and serve at the discretion of the board of directors, rather than for specific terms of office, subject to the terms of employment agreements, where applicable. The board of directors is authorized to appoint persons to the offices set forth in our bylaws as it deems appropriate. The Company's bylaws provide that our officers may consist of a Chairman of the Board, Chief Executive Officer, Chief Financial Officer, President, one or more Vice Presidents, Secretary, Treasurer, one or more Assistant Secretaries and such other offices as may be determined by the board of directors.

Director Independence

The Nasdaq listing standards require that a majority of our Board of Directors be independent. An "independent director" is defined generally as a person who has no material relationship with the listed company (either directly or as a partner, stockholder or officer of an organization that has a relationship with the company). The Company's independent directors expect to have regularly scheduled meetings at which only independent directors are present. Any affiliated transactions will be on terms no less favorable to the Company than could be obtained from independent parties. The Company's Board of Directors will review and approve all affiliated transactions with any interested director abstaining from such review and approval.

Based on information provided by each director concerning his or her background, employment and affiliations, the Board has determined that Paul Burton, James Intrater, Stanley K. Lau, MD and Oded Levy, representing four of the Company's seven directors, do not have a relationship that would interfere with the exercise of independent judgment in carrying out the responsibilities of a director and that each of these directors is an "independent director" as defined under the listing standards of Nasdaq and applicable SEC rules. In making these determinations, the Company Board considered the current and prior relationships that each non-employee director has with the Company and all other facts and circumstances that the Company Board deemed relevant in determining their independence, including the beneficial ownership of the Company capital stock by each non- employee director, and the transactions involving them. See "Certain Cardio Relationships and Related Persons Transactions."

Board Committees

The standing committees of the Cardio Board consist of an audit committee, a compensation committee and a nominating and corporate governance committee. The board of directors may from time to time establish other committees.

Cardio's chief executive officer and other executive officers regularly report to the non-executive directors and the audit, the compensation and the nominating and corporate governance committees to ensure effective and efficient oversight of our activities and to assist in proper risk management and the ongoing evaluation of management controls.

Audit Committee

Cardio has an audit committee consisting of Paul Burton, James Intrater and Oded Levy, with Mr. Levy serving as the chair of the committee. The Cardio Board has determined that each member of the audit committee qualifies as an independent director under the independence requirements of the Sarbanes-Oxley Act, Rule 10A-3 under the Exchange Act and Nasdaq listing requirements. The Cardio Board has determined that Mr. Levy qualifies as an "audit committee financial expert," as defined in Item 407(d)(5) of Regulation S-K, and that he possesses financial sophistication, as defined under the rules of Nasdaq.

The audit committee's responsibilities include, among other things:

- reviewing and discussing with management and the independent auditor the annual audited financial statements, and recommending to the Board whether the audited financial statements should be included in our Form 10-K;
- discussing with management and the independent auditor significant financial reporting issues and judgments made in connection with the preparation of our financial statements;
- discussing with management major risk assessment and risk Management policies;
- monitoring the independence of the independent auditor;

- verifying the rotation of the lead (or coordinating) audit partner having primary responsibility for the audit and the audit partner responsible for reviewing the audit as required by law;
- reviewing and approving all related-party transactions;
- inquiring and discussing with management our compliance with applicable laws and regulations;
- pre-approving all audit services and permitted non-audit services to be performed by our independent auditor, including the fees and terms of the services to be performed;
- appointing or replacing the independent auditor;
- determining the compensation and oversight of the work of the independent auditor (including resolution of disagreements between Management and the independent auditor regarding financial reporting) for the purpose of preparing or issuing an audit report or related work;
- reviewing and approving any annual or long-term incentive cash bonus or equity or other incentive plans in which our executive officers may participate;
- establishing procedures for the receipt, retention and treatment of complaints received by us regarding accounting, internal accounting controls or reports which raise material issues regarding our financial statements or accounting policies; and
- approving reimbursement of expenses incurred by our management team in identifying potential target businesses.

The board of directors has adopted a written charter for the audit committee that is available on our website.

Compensation Committee

Cardio has a compensation committee consisting of James Intrater, Stanley Lau and Oded Levy with Dr. Lau serving as chair of the committee. The Cardio Board has determined that each member of the compensation committee qualifies as an independent director under the independence requirements of the Sarbanes-Oxley Act, Rule 10A-3 under the Exchange Act and Nasdaq listing requirements.

The compensation committee's responsibilities include, among other things:

- establishing, reviewing, and approving our overall executive compensation philosophy and policies ;
- reviewing and approving on an annual basis the corporate goals and objectives relevant to our Chief Executive Officer's compensation, evaluating our Chief Executive Officer's performance in light of such goals and objectives and determining and approving the remuneration (if any) of our Chief Executive Officer based on such evaluation;
- reviewing and approving the compensation of all of our other executive officers;
- approving reimbursement of expenses incurred by our management team in identifying potential target businesses.
- reviewing our executive compensation policies and plans;
- receiving and evaluating performance target goals for the senior officers and employees (other than executive officers) and reviewing periodic reports from the CEO as to the performance and compensation of such senior officers and employees;
- implementing and administering our incentive compensation equity-based remuneration plans;
- reviewing and approving any annual or long-term incentive cash bonus or equity or other incentive plans in which our executive officers may participate;
- reviewing and approving for our chief executive officer and other executive officers any employment agreements, severance arrangements, and change in control agreements or provisions;
- reviewing and discussing with Management the Compensation Discussion and Analysis set forth in Securities and Exchange Commission Regulation S-K, Item 402, if required, and, based on such review and discussion, determine whether to recommend to the Board that the Compensation Discussion and Analysis be included in our annual report or proxy statement the annual meeting of stockholders;
- assisting management in complying with our proxy statement and annual report disclosure requirements;
- approving all special perquisites, special cash payments and other special compensation and benefit arrangements for our executive officers and employees;
- if required, producing a report on executive compensation to be included in our annual proxy statement;
- reviewing and recommending to the Board for approval the frequency with which we will conduct Say-on-Pay Votes, taking into account the results of the most recent stockholder advisory vote on frequency of Say-on-Pay Votes required by Section 14A of the Exchange Act, and review and recommend to the Board for approval the proposals regarding the Say-on-Pay Vote and the frequency of the Say-on-Pay Vote to be included in our proxy statements filed with the SEC;
- conducting an annual performance evaluation of the committee; and
- reviewing, evaluating and recommending changes, if appropriate, to the remuneration for directors.

The board of directors has adopted a written charter for the compensation committee that is available on our website.

Compensation Committee Interlocks and Insider Participation

None of our executive officers serves as a member of the compensation committee of the board of directors (or other committee performing equivalent functions) of any entity that has one or more executive officers serving on our board of directors.

Nominating and Corporate Governance Committee

Cardio has a nominating and corporate governance committee consisting of James Intrater, Stanley Lau and Paul Burton, with Mr. Burton serving as chair of the committee. The Cardio Board has determined that each member of the nominating and corporate governance committee qualifies as an independent director under the independence requirements of the Sarbanes-Oxley Act, Rule 10A-3 under the Exchange Act and Nasdaq listing requirements.

The nominating and corporate governance committee's responsibilities include, among other things:

- review and assess and make recommendations to the board of directors regarding desired qualifications, expertise and characteristics sought of board members;
- identify, evaluate, select or make recommendations to the board of directors regarding nominees for election to the board of directors;
- develop policies and procedures for considering stockholder nominees for election to the board of directors;
- review the Company's succession planning process for Company's chief executive officer, and assist in evaluating potential successors to the chief executive officer;
- review and make recommendations to the board of directors regarding the composition, organization and governance of the board and its committees;
- review and make recommendations to the board of directors regarding corporate governance guidelines and corporate governance framework;
- oversee director orientation for new directors and continuing education for directors;
- oversee the evaluation of the performance of the board of directors and its committees;
- review and monitor compliance with the Company's code of business conduct and ethics; and
- administer policies and procedures for communications with the non-management members of the Company's Board of Directors.

The board of directors has adopted a written charter for the nominating and corporate governance committee that is available on our website.

Guidelines for Selecting Director Nominees

The guidelines for selecting nominees generally provide that persons to be nominated:

- should have demonstrated notable or significant achievements in business, education or public service;
- should possess the requisite intelligence, education and experience to make a significant contribution to the Board of Directors and bring a range of skills, diverse perspectives and backgrounds to its deliberations; and
- should have the highest ethical standards, a strong sense of professionalism and intense dedication to serving the interests of the stockholders.

The nominating and governance committee will consider a number of qualifications relating to management and leadership experience, background and integrity and professionalism in evaluating a person's candidacy for membership on the Board of Directors. The nominating and governance committee may require certain skills or attributes, such as financial or accounting experience, to meet specific board needs that arise from time to time and will also consider the overall experience and makeup of its members to obtain a broad and diverse mix of board members. The nominating and governance committee does not distinguish among nominees recommended by stockholders and other persons.

Code of Ethics

The Company has adopted a written code of business conduct and ethics that applies to its principal executive officer, principal financial or accounting officer or person serving similar functions and all of our other employees and members of our board of directors. The code of ethics codifies the business and ethical principles that govern all aspects of our business. Cardio intends to make any legally required disclosures regarding amendments to, or waivers of, provisions of our code of ethics on our website.

Conflicts of Interest

Potential investors should be aware of the following potential conflicts of interests:

- None of our officers and directors is required to commit their full time to our affairs and, accordingly, they may have conflicts of interest in allocating their time among various business activities.
- In the course of their other business activities, our officers and directors may become aware of investment and business opportunities which may be appropriate for presentation to our company as well as the other entities with which they are affiliated. Our Management has pre-existing fiduciary duties and contractual obligations to such entities (as well as to us) and may have conflicts of interest in determining to which entity a particular business opportunity should be presented.
- Our officers and directors may in the future become affiliated with entities engaged in business activities similar to those intended to be conducted by our company.

The conflicts described above may not be resolved in our favor.

All ongoing and future transactions between us and any of our management team or their respective affiliates, will be on terms believed by us to be no less favorable to us than are available from unaffiliated third parties. Such transactions will require prior approval by a majority of our uninterested "independent" directors or the members of our board of directors who do not have an interest in the transaction, in either case who had access, at our expense, to our attorneys or independent legal counsel. We will not enter into any such transaction unless our disinterested "independent" directors determine that the terms of such transaction are no less favorable to us than those that would be available to us with respect to such a transaction from unaffiliated third parties.

Limitation on Liability and Indemnification of Officers and Directors

The Company intends to enter into indemnification agreements with each of its directors and executive officers that may be broader than the specific indemnification provisions contained in the DGCL. These indemnification agreements, which have been authorized for execution by the Cardio board of directors, requires the Company, among other things, to indemnify its directors and executive officers against liabilities that may arise by reason of their status or service. These indemnification agreements also require the Company to advance all expenses reasonably and actually incurred by its directors and executive officers in investigating or defending any such action, suit or proceeding. Our By-laws provide that Cardio must indemnify and advance expenses to Cardio's directors and officers to the fullest extent authorized by the DGCL. We believe tha these agreements and By-laws provisions are necessary to attract and retain qualified individuals to serve as directors and executive officers.

Cardio maintains insurance policies under which its directors and officers are insured, within the limits and subject to the limitations of those policies, against certain expenses in connection with the defense of, and certain liabilities which might be imposed as a result of, actions, suits, or proceedings to which they are parties by reason of being or having been its directors or officers. The coverage provided by these policies may apply whether or not the Company would have the power to indemnify such person against such liability under the provisions of the DGCL. At present, we are not aware of any pending litigation or proceeding involving any person who will be one of the Company's directors or officers or is or was one of its directors or officers, or is or was one of its directors or officers serving at its request as a director, officer, employee or agent of another corporation, partnership, joint venture, trust or other enterprise, for which indemnification is sought, and we are not aware of any threatened litigation that may result in claims for indemnification.

The DGCL authorizes corporations to limit or eliminate the personal liability of directors of corporations and their stockholders for monetary damages for breaches of directors' fiduciary duties, subject to certain exceptions. Our Second Amended and Restated Certificate of Incorporation includes a provision that eliminates the personal liability of directors for damages for any breach of fiduciary duty as a director where, in civil proceedings, the person acted in good faith and in a manner that person reasonably believed to be in or not opposed to the best interests of our Company or, in criminal proceedings, where the person had no reasonable cause to believe that his or her conduct was unlawful.

The limitation of liability, advancement and indemnification provisions in our Second Amended and Restated Certificate of Incorporation and our By-laws may discourage stockholders from bringing 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 Cardio and our stockholders. In addition, your investment may be adversely affected to the extent Cardio pays the costs of settlement and damage awards against directors and officer pursuant to these indemnification provisions.

There is currently no pending material litigation or proceeding involving any of Cardio's directors, officers, or employees for which indemnification is sought.

Section 16(a) Beneficial Ownership Reporting Compliance

Section 16(a) of the Securities Exchange Act of 1934, as amended, or the Exchange Act, requires our executive officers, directors, and persons who beneficially own more than 10% of a registered class of our equity securities to file with the Securities and Exchange Commission initial reports of ownership and reports of changes in ownership of our shares of common stock and other equity securities. These executive officers, directors, and greater than 10% beneficial owners are required by SEC regulation to furnish us with copies of all Section 16(a) forms filed by such reporting persons.

Based solely on our review of such forms furnished to us and written representations from certain reporting persons, we believe that, during the fiscal year ended December 31, 2023, our directors, executive officers, and ten percent stockholders complied with all Section 16(a) filing requirements.

Item 11. Executive Compensation

Overview

This section discusses the material components of the executive compensation program for our executive officers who are named in the "2023 Summary Compensation Table" below. For the year ended December 31, 2023, our "named executive officers" ("NEOs") and their positions were as follows:

- Meeshanthini V. Dogan, Chief Executive Officer;

- Warren Hosseinion, Non-executive Chairman of the Board*; and
- Elisa Luqman, Chief Financial Officer

*Dr. Hosseinion provides ongoing services to our company as Chairman of the Board and as a consultant. As such, he is not an executive officer and would not be included in the executive compensation tables or accompanying narrative as an NEO under SEC disclosure rules. However, because his contractual compensation is significant and would be payable to him, even if he were no longer our Chairman, we are treating him as an NEO in this Item 11 in the interest of full disclosure of the compensation payable to the highest paid persons who work for our company. Dr. Hosseinion is not considered a Named Executive Officer for any purpose other than the following disclosures.

2023 Summary Compensation Table

The following table sets forth information concerning the compensation of our named executive officers for fiscal years ended December 31, 2023 and 2022.

Current Officers Name & Principal Position	Year	Salary ($)	Bonus [3]	Stock	Option Awards [2]	All Other Compensation ($)	Total
		($)	($)	($)	($)	($)	($)
Meeshanthini V. Dogan,	2023	300,000	0	0	341,640	7,253(1)	648,893
CEO	2022	175,000	250,000	0	4,105,856	8,897(1)	4,539,753
Warren Hosseinion,	2023	300,000	0	0	155,291	0	455,291
Chairman	2022	50,000	250,000	0	2,052,928	30,000(4)	2,382,928
Elisa Luqman,	2023	275,000	0	0	72,469	0	347,469
CFO	2022	55,833	100,000	0	1,026,464	20,000(4)	1,202,297

(1) All Other Compensation includes Cardio's contribution to the Company's 401(k) account on behalf of the executive and health and dental insurance coverage.

(2) Discretionary stock option grants made in 2023 by the Compensation Committee. The 2023 amounts reflect the grant date fair values of performance awards based upon the Nasdaq closing stock price of $1.26 on the date of grant. Discretionary stock option grants were made in 2022 by Legacy Cardio and subsequently exchanged for options under the Cardio Diagnostics Holdings, Inc. 2022 Equity Incentive Plan in connection with the Closing of the Business Combination. All outstanding 2022 options became immediately vested at the Closing. The 2022 amounts reflect the grant date fair values of performance awards based upon the Nasdaq closing stock price of $5.99 on the date of the Closing of the Business Combination. The amounts reported do not reflect compensation actually received.

(3) Discretionary cash bonus paid in 2022, for 2021 and 2022 performance and completion of the Business Combination.

(4) Consulting compensation paid prior to Closing of the Business Combination.

Narrative to the Summary Compensation Table

2023 Base Salary

The named executive officers receive a base salary to compensate them for services rendered to our company. The base salary payable to each named executive officer is intended to provide a fixed component of compensation reflecting the executive's skill set, experience, role and responsibilities. In 2023, the base salaries paid to each of Dr. Dogan, Dr. Hosseinion and Ms. Luqman are set forth in the "Summary Compensation Table" above in the column titled "Salary." Each of the NEOs has entered into an employment agreement (or, in the case of Dr. Hosseinion, a Non-Executive Chairman and Consulting Agreement), which became effective as of the Closing of the Business Combination. A brief summary of those agreements is set forth below under the caption, "Agreements with Our Executive Officers and Non-Executive Chairman of the Board."

Annual Bonuses

We do not currently maintain an annual bonus program for our employees, including our named executive officers. However, the employment agreements and, in the case of Dr. Hosseinion, his Non-Executive Chairman and Consulting Agreement, provide that our named executive officers are eligible to receive an annual cash bonus based on the extent to which, in the discretion of the Board, each such person achieves or exceeds specific and measurable individual and Company performance objectives. The Board did not award any annual bonuses in 2023.

2022 Cash Performance Incentives

Prior to the Closing of the Business Combination, Legacy Cardio's Board of Directors determined that it was in Cardio's best interests to award cash performance incentive payments to certain Legacy Cardio executive officers and directors in recognition of each such individual's efforts required in connection with: (i) successfully completing the private placements of Legacy's Cardio's Common Stock in 2022, and (ii) since May 27, 2022, assisting in the preparation and filing with the SEC of the registration statement on Form S-4 relating to the Business Combination and related matters, as well as amendments thereto, responding to comments thereon made by the SEC applicable to Legacy Cardio, facilitating the completion of the SEC's review thereof, including assisting in seeking to cause the registration statement to be declared effective, and handling numerous other matters incidental to consummating the Business Combination pursuant to the Merger Agreement. The Legacy Cardio Board awarded the cash bonuses to the named executive officers, as reflected in the "Bonus" column of the Summary Compensation Table, which awards were pre-approved by the Mana Board of Directors.

Equity Compensation

Legacy Cardio established and maintained a 2022 Equity Incentive Plan (the "2022 Legacy Plan") pursuant to which Legacy Cardio granted stock options to certain executive officers, directors, employees and consultants. Options were granted in May 2022 under the Legacy Cardio Plan, none of which would vest until the Closing of the Business Combination, if ever. Unvested stock options granted pursuant to the 2022 Legacy Plan were exchanged for stock options in the Company under the Cardio Diagnostics Holdings, Inc. 2022 Equity Incentive Plan (the "2022 Equity Plan"), adopted by the Mana Board of Directors and approved by the Mana stockholders in connection with the Business Combination. The options granted to the named executive officers that were exchanged in connection with the Business Combination are reflected in the column "Option Awards" in the Summary Compensation Table for 2022. The number of options granted to each named executive officer is the number of previously-granted Legacy Cardio options, as adjusted for the merger exchange ratio.

The 2022 Equity Plan, as adopted, provides for the grant of up to 3,265,516 shares of Common Stock upon exercise of granted options, awards of restricted stock units, rewards of restricted stock and other equity awards as may be determined by the Board of Directors. In the discretion of the Board, the number of shares of Common Stock available under the 2022 Plan may be increased as of January 1 of each year, without additional stockholder approval. After application of the Business Combination exchange ratio of 3.427259, the 511,843 Legacy Cardio stock options were exchanged for 1,754,219 stock options under the 2022 Equity Plan at an exercise price of $3.90 per share. All of the exchanged options vested and became immediately exercisable upon the Closing of the Business Combination. The Board did not increase the aggregate number of shares available under the 2022 Equity Plan on January 1, 2023 but the 2022 Equity Plan was increased by 1,071,425 shares as of January 1, 2024. In the future, we may grant cash and equity incentive awards to directors, employees (including our named executive officers) and consultants in order to continue to attract, motivate and retain the talent for which we compete.

A total of 377,370 shares were available for issuance under the 2022 Equity Plan at December 31, 2023. At December 31, 2023, there were 2,584,599 options outstanding for the purchase of Common Stock, all of which were vested and exercisable.

The following table sets forth information as of December 31, 2023 regarding Common Stock that may be issued under the 2022 Equity Plan, which, as of the date of this report, is the only equity compensation plan that has been adopted by our Board of Directors.

Plan Category	(A) Number of Securities to be issued upon exercise of outstanding options, warrants and rights	(B) Weighted average per share exercise price of outstanding options, warrants and rights	(C) Number of Securities remaining available for future issuance under equity compensation plans (excluding securities reflected in column (A))
Equity compensation plans approved by security holders	2,584,599(1)	$ 3.06(2)	377,370(3)
Equity compensation plans not approved by security holders	—	—	—

(1) Includes 2,584,599 outstanding options to purchase shares of Common Stock under the 2022 Equity Plan.

(2) 1,759,599 outstanding options are exercisable at $3.90, and 825,000 outstanding options are exercisable at $1.26 subject to adjustment for stock splits, reverse stock splits and other similar events of recapitalization.

(3) This amount includes the deduction of 303,547 shares in settlement of RSUs issued in 2023 to our independent directors. This amount does not include any additional shares that may become available for future issuance under the 2022 Equity Plan pursuant to the automatic increase to the share reserve on January 1 of each of our calendar years through 2027 (each, an "Evergreen Date") by the number of shares equal to the lesser of (i) 7% of the total number of shares of Common Stock outstanding on the December 31st immediately preceding the applicable Evergreen Date and (ii) such lesser number of shares of Common Stock as determined to be appropriate by the committee in its sole discretion. Effective January 1, 2024, the 2022 Equity Plan increased by 1,071,425 shares pursuant to the evergreen provision of the plan.

Refer to Note 10 to the consolidated financial statements included in this annual report for additional information relating to outstanding options .

Other Elements of Compensation

Retirement Plan

We maintain a 401(k) retirement savings plan for our employees, including our named executive officers, who satisfy certain eligibility requirements. The Internal Revenue Code allows eligible employees to defer a portion of their compensation, within prescribed limits, on a pre-tax basis through contributions to the 401(k) plan. We believe that providing a vehicle for tax-deferred retirement savings though our 401(k) plan adds to the overall desirability of our executive compensation package and further incentivizes our employees, including our named executive officers, in accordance with our compensation policies.

Employee Benefits and Perquisites

Health/Welfare Plans. All of our full-time employees, including our named executive officers, are eligible to participate in our health and welfare plans, including:

- medical, dental and vision benefits;
- medical and dependent care flexible spending accounts;
- life insurance and accidental death and dismemberment;

We believe the benefits described above are necessary and appropriate to provide a competitive compensation package to our employees, including our named executive officers. We do not provide any perquisites to our named executive officers.

No Tax Gross-Ups

We do not make gross-up payments to cover our named executive officers' personal income taxes that may pertain to any of the compensation or benefits paid or provided by our Company.

Outstanding Equity Awards at Fiscal Year-End Table

The following table summarizes the number of shares of common stock underlying outstanding equity incentive plan awards for each named executive officer as of December 31, 2023. We have made no stock awards under the 2022 Plan and accordingly, that portion of the table has been omitted.

	Option Awards				
Name	Number of Securities Underlying Unexercised Options (#)(1)		Equity Incentive Plan Awards: Number of Securities Underlying Unexercised Unearned Options (#)	Option Exercise Price ($)	Option Expiration Date
	Exercisable	Unexercisable			
Meeshanthini V. Dogan	272,250	—	—	$ 1.26	6/23/2033
Meeshanthini V. Dogan	685,452	—	—	$ 3.90	5/6/2032
Warren Hosseinion	123,750	—	—	$ 1.26	6/23/2033
Warren Hosseinion	342,726	—	—	$ 3.90	5/6/2032
Elisa Luqman	57,750	—	—	$ 1.26	6/23/2033
Elisa Luqman	171,363	—	—	$ 3.90	5/6/2032

Agreements with Our Executive Officers and Non-Executive Chairman of the Board

In connection with preparations for the Business Combination, Cardio executed employment agreements as of May 27, 2022 with each person expected to be named an executive officer of the combined entity. Other than the agreement with Khullani Abdullahi, whose agreement was effective as of May 19, 2022, the agreements became effective upon Closing of the Business Combination. The principal terms of each of agreements is as follows:

Employment Agreement between Cardio and Meeshanthini V. Dogan (Chief Executive Officer)

Dr. Dogan's five-year employment agreement provides for (i) an annual base salary of $300,000, (ii) eligibility to receive an annual cash bonus based on the extent to which, in the discretion of the Board, Dr. Dogan achieves or exceeds specific and measurable individual and Company performance objectives, and (iii) eligibility to participate in any long-term incentive plan that is made available to similarly positioned executives, employee benefit or group insurance plans maintained from time to time by Cardio. Long-term incentive plan awards may include cash, or equity awards settled in shares of Company stock, including but not limited to stock options, restricted stock and performance shares. If Dr. Dogan were to leave the Company as a "Good Leaver," as defined in the employment agreement, terms of any long-term incentive award will be deemed satisfied immediately prior to such termination and as such, all awards and grants will be deemed fully vested. In addition, Dr. Dogan will be reimbursed for her reasonable and usual business expenses incurred on behalf of the Company. Severance benefits will be payable in the event Dr. Dogan's termination is either by the Company without cause or by her with "good reason," as defined in the agreement. In such event and in addition to accrued salary benefits as of the date of termination, the Company will pay Dr. Dogan an amount equal to a (x) two times the sum of her most recent base salary and target annual bonus and (y) an amount in cash equal to the Company's premium amounts paid for her coverage under group medical, dental and vision programs for a period of 24 months. The agreement also contains customary confidentiality, non-solicitation, non-competition and cooperation provisions. The employment agreement will automatically renew for an additional year following the initial term and any renewal term, unless either party provides 60-days' written notice before the end of the then-current term. The Company may terminate Dr. Dogan's employment without cause (as defined in the agreement) by providing 60 days' advance written notice. Dr. Dogan may terminate her employment for any reason.

Non-Executive Chairman and Consulting Agreement between Cardio and Warren Hosseinion

Cardio has retained Dr. Hosseinion under a five-year consulting agreement to serve as Non-Executive Chairman of the Board following the Merger and to provide other services as requested. Upon expiration of such provision, the agreement may be renewed for an additional one-year term. In addition to his duties as Chairman, the agreement provides that Dr. Hosseinion will provide consulting services assisting management in developing business strategy and business plans, identifying business opportunities and identifying strategic relationships and strategies to further develop the Company's brand. In the event he is not reelected as Chairman of the Board, the terms of this agreement will continue strictly as a consulting services agreement. Conversely, if his consulting services are terminated, such termination will not affect his Chairman Services, provided that he remains eligible to serve as Chairman. For his Chairman services and consulting services, the agreement provides for a fee of $300,000 per year payable in monthly installments of $25,000. In addition, Dr. Hosseinion is entitled to be awarded any equity compensation otherwise payable to Board members in connection with their service on the Board and to be reimbursed for all reasonable and necessary business expenses incurred in the performance of his consulting services and Chairman services. If Dr. Hosseinion's services are terminated by the Company other than for Cause (as defined in the agreement), including any discharge without Cause, liquidation or dissolution of the Company, or a termination caused by death or Disability (as defined in the agreement), the Company will pay Dr. Hosseinion (or his estate) the consulting fees equal to two times his annual consulting compensation, payable within 60 days, in one lump sum, plus any expenses owing for periods prior to and including the date of termination of the consulting services. The agreement also contains customary confidentiality, non-solicitation, non-disparagement and cooperation provisions. Either party may terminate the agreement without cause after giving prior written notice to the other party. The agreement may be terminated by the Company at any time for cause, as defined in the agreement.

Employment Agreement between Cardio and Elisa Luqman (Chief Financial Officer)

Ms. Luqman's five-year employment agreement provides for (i) an annual base salary of $275,000, (ii) eligibility to receive an annual cash bonus based on the extent to which, in the discretion of the Board, Ms. Luqman achieves or exceeds specific and measurable individual and Company performance objectives, and (iii) eligibility to participate in any long-term incentive plan that is made available to similarly positioned executives, employee benefit or group insurance plans maintained from time to time by Cardio. Long-term incentive plan awards may include cash, or equity awards settled in shares of Company stock, including but not limited to stock options, restricted stock and performance shares. If Ms. Luqman were to leave the Company as a "Good Leaver," as defined in the employment agreement, terms of any long-term incentive award will be deemed satisfied immediately prior to such termination and as such, all awards and grants will be deemed fully vested. In addition, Ms. Luqman will be reimbursed for her reasonable and usual business expenses incurred on behalf of the Company. Severance benefits will be payable in the event Ms. Luqman's termination is either by the Company without cause or by her with "good reason," as defined in the agreement. In such event and in addition to accrued salary benefits as of the date of termination, the Company will pay Ms. Luqman an amount equal to a (x) the sum of her most recent base salary and target annual bonus and (y) an amount in cash equal to the Company's premium amounts paid for her coverage under group medical, dental and vision programs for a period of 12 months, provided that she has elected continued coverage under COBRA. The agreement also contains customary confidentiality, non-solicitation, non-competition and cooperation provisions. The employment agreement will automatically renew for an additional year following the initial term and any renewal term, unless either party provides 60-days' written notice before the end of the then-current term. The Company may terminate Ms. Luqman's employment without cause (as defined in the agreement) by providing 60 days' advance written notice. Ms. Luqman may terminate her employment for any reason.

Director Compensation

The following individuals served as non-employee directors of the Company for all or part of 2023 (other than Dr. Hosseinion, who, as discussed above, is being treated as an NEO for purposes of the compensation disclosure in this Annual Report): Paul Burton, James Intrater, Stanley K. Lau, Oded Levy and Brandon Sim. The following table sets forth information concerning the compensation for our non-employee directors for services rendered during the year ended December 31, 2023. Additionally, we reimburse our non-employee directors for reasonable travel and other out-of-pocket expenses incurred in connection with attending board of director and committee meetings or undertaking other business on behalf of Cardio.

Name	Fees Earned or Paid in Cash ($)	Stock Awards ($)	All Other Compensation ($)	Total ($)
Paul Burton(1)	—	—	—	—
James Intrater	—	50,000	—	—
Stanley K. Lau	—	50,000	—	—
Oded Levy	—	50,000	—	—
Brandon Sim(2)	—	50,000	—	—

(1) Paul Burton was elected to the Board at the December 18, 2023 Annual Meeting of Stockholders.

(2) Brandon Sim did not stand for re-election at the 2023 Annual Meeting but did receive shares of Common Stock upon vesting and settlement of previously awarded RSUs on December 31, 2023.

During 2023, Cardio compensated its non-employee, independent directors for service as a director with Restricted Stock Units ("RSUs") in the amount of $12,500 in RSU awards quarterly. The first such award was made on June 30, 2023 for $25,000 to compensate for two quarters of service. Thereafter, on September 30, 2023 and December 31, 2023, each independent director received $12,500 in RSU awards. RSUs vested and were settled on the date of each respective grant. The number of shares of Common Stock into which the RSUs were settled were based on the closing price of our Common Stock on June 30, 2023, September 30, 2023 and December 31, 2023, respectively.

The compensation committee has determined that the same type and level of compensation as 2023 be granted to those persons serving as non-employee directors in 2024. On January 23, 2024, each currently-serving non-employee director was awarded $50,000 in RSUs, which RSUs will vest quarterly. Subject to continued service with the Company on each respective vesting date, the RSUs shall vest and be settled in shares of Common Stock based on the closing price of our Common Stock on each respective vesting date: (i) $12,500 in value on March 31, 2024; (ii) $12,500 in value on June 30, 2024; (iii) $12,500 in value on September 30, 2024; and (iv) $12,500 in value on December 31, 2024.

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

The following table sets forth information regarding the beneficial ownership of the Company's Common Stock as of April 1, 2024 by:

- each person known to the Company to be the beneficial owner of more than 5% of the Company's Common Stock;
- each person who is a "named executive officer" or a director of the Company and
- all of the Company's executive officers and directors as a group.

Beneficial ownership is determined in accordance with SEC rules and includes voting or investment power with respect to securities. Except as indicated by the footnotes below, the Company believes, based on the information furnished to it as of the Closing of the Business Combination, that the persons named in the table below have, sole voting and investment power with respect to all stock that they beneficially own, subject to applicable community property laws. All Company stock subject to options or warrants exercisable within 60 days of the date of the table are deemed to be outstanding and beneficially owned by the persons holding those options or warrants for the purpose of computing the number of shares beneficially owned and the percentage ownership of that person. They are not, however, deemed to be outstanding and beneficially owned for the purpose of computing the percentage ownership of any other person.

Subject to the paragraph above, percentage ownership of outstanding shares is based on 21,591,119 shares of the Company's Common Stock outstanding as of April 1, 2024.

Name and Address of Beneficial Owner(1)	Amount and Nature of Beneficial Ownership	Approximate Percentage of Outstanding Shares
Directors, Executive Officers and Greater than 5% Holders		
Meeshanthini V. Dogan(2)	3,020,422	9.04%
Robert Philibert(3)	2,455,257	7.35%
Warren Hosseinion(4)	618,248	1.85%
Elisa Luqman(5)	322,772	0.97%
James Intrater	62,793	—
Stanley K. Lau	91,522	—
Oded Levy	62,793	—

Paul Burton	—	—
Timur Dogan(6)	563,812	1.69%
Khullani Abdullahi(7)	318,682	0.95%
All Executive Officers and Directors as a Group (10 individuals)	7,516,301	22.50%

***** Less than 1%.

(1) Unless otherwise noted, the address for the persons in the table is 311 West Superior Street, Suite 444, Chicago IL 60654.

(2) Meeshanthini Dogan and Timur Dogan are married. The beneficial ownership of Meeshanthini Dogan reflected in the table includes the shares and options of Timur Dogan. Meeshanthini Dogan's direct ownership is 1,586,464 shares of common stock and 1,433,958 shares issuable upon exercise of options. Dr. Dogan may be deemed to be the indirect beneficial owner of the securities owned by her husband; however, she disclaims beneficial ownership of the shares held indirectly, except to the extent of her pecuniary interest.

(3) Shares of common stock reflected in the table as beneficially owned by Dr. Philibert are held of record by BD Holdings, Inc., whose address is 2500 Crosspark Road, Suite W245, Coralville, IA 52241. BD Holdings, Inc. is a corporation owned and controlled by Dr. Philibert. Dr. Philibert disclaims beneficial ownership of all such indirectly-owned shares except to the extent of his pecuniary interest in such corporations. Also includes 805,465 shares of Common Stock issuable upon exercise of options that are currently exercisable.

(4) Includes 502,195 shares of common stock issuable upon exercise of options.

(5) Includes 264,832 shares of common stock issuable upon exercise of options.

(6) Timur Dogan and Meeshanthini Dogan are married. The beneficial ownership of Timur Dogan reflected in the table includes the shares and options of Meeshanthini Dogan. Timur Dogan's direct ownership is 128,345 shares of common stock and 435,467 shares issuable upon exercise of options. Dr. Dogan may be deemed to be the indirect beneficial owner of the securities owned by his wife; however, he disclaims beneficial ownership of the shares held indirectly, except to the extent of his pecuniary interest.

(7) Includes 304,128 shares of common stock issuable upon exercise of options.

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

There have been no transactions since January 1, 2023 to which we have been a party in which the amount involved exceeded or will exceed the lesser of $120,000 or 1% of the average of our total assets at year end for the last two completed fiscal years, and in which any of our directors, executive officers or, to our knowledge, beneficial owners of more than 5% of our capital stock or any member of the immediate family of any of the foregoing persons had or will have a direct or indirect material interest, other than transactions that are described under the section "Executive and Director Compensation."

Cardio has an exclusive, worldwide patent license of the Core Technology from the University of Iowa Research Foundation (UIRF). Under UIRF's Inventions Policy inventors are generally entitled to 25% of income from earnings from their inventions. Consequently, Meeshanthini Dogan and Robert Philibert will benefit from this policy.

Timur Dogan, spouse of Meeshanthini (Meesha) Dogan (the Company's Co-Founder, Chief Executive Officer and Director), has been a full-time employee of the Company since August 2019. In 2021, he was paid $37,500 in salary and an additional $4,765 in benefits.

In May 2022, Legacy Cardio granted 511,843 stock options to its executive officers and directors. These options were exchanged for an aggregate of 1,754,219 options under the 2022 Equity Incentive Plan, The Options fully vested and became fully exercisable upon Closing of the Business Combination and have an exercise price of $3.90 per share (as adjusted for the Exchange Ratio) with an expiration date of May 6, 2032.

At the Closing of the Business Combination, Dr. Dogan, Dr. Philibert, Ms. Luqman, Dr. Dogan and Ms. Abdullahi each entered into an Invention and Non-Disclosure Agreement. An integral part of the Invention and Non-Disclosure Agreement is the disclosure by the employee of any discoveries, ideas, inventions, improvements, enhancements, processes, methods, techniques, developments, software and works of authorship ("developments") that were created, made, conceived or reduced to practice by the employee prior to his or her employment by Cardio and that are not assigned to the Company. Dr. Philibert's agreement lists certain developments that are epigenetic methods unrelated to the current mission of Cardio and that were developed separate and apart from Cardio. There is no assurance that as the Company broadens the scope of its products and services that one or more of Dr. Philibert's developments could be relevant. Under the agreement, all rights to the developments listed by Dr. Philibert are his sole property and their use, if desired by the Company, would be in the sole discretion of Dr. Philibert, who is under no obligation to license or otherwise grant permission to the Company to use them.

Related Party Policy

The audit committee of the board of directors had adopted a policy setting forth the policies and procedures for its review and approval or ratification of "related party transactions." The policy provides that a "related party transaction" is defined in the policy as any consummated or proposed transaction or series of transactions: (i) in which the Company was or is to be a participant; (ii) the amount of which exceeds (or is reasonably expected to exceed) the lesser of $120,000 or 1% of the average of the Company's total assets at year-end for the prior two completed fiscal years in the aggregate over the duration of the transaction (without regard to profit or loss); and (iii) in which a "related party" had, has or will have a direct or indirect material interest. "Related parties" under this policy included: (i) Cardio's directors, nominees for director or executive officers; (ii) any record or beneficial owner of more than 5% of any class of Cardio's voting securities; (iii) any immediate family member of any of the foregoing if the foregoing person is a natural person; and (iv) any other person who maybe a "related person" pursuant to Item 404 of Regulation S-K under the Exchange Act. Pursuant to the policy, the audit committee would consider (i) the relevant facts and circumstances of each related party transaction, including if the transaction is on terms comparable to those that could be obtained in arm's-length dealings with an unrelated third party, (ii) the extent of the related party's interest in the transaction, (iii) whether the transaction contravenes our code of ethics or other policies, (iv) whether the audit committee believes the relationship underlying the transaction to be in the best interests of Cardio and its stockholders and (v) the effect that the transaction may have on a director's status as an independent member of Cardio's board and on his or her eligibility to serve on Cardio's board's committees. The policy requires that the Company's management present to the audit committee each proposed related party transaction, including all relevant facts and circumstances relating thereto. Under the policy, the Company is permitted to consummate related party transactions only if the audit committee approves or ratifies the transaction in accordance with the guidelines set forth in the policy. The policy does not permit any director or executive officer to participate in the discussion of, or decision concerning, a related person transaction in which he or she is the related party.

Item 14. Principal Accounting Fees and Services

Fees Paid to the Independent Registered Public Accounting Firm

The following table presents fees for professional audit services and other services rendered by Prager Metis for the fiscal years ended December 31, 2023 and 2022:

	For the Year Ended December 31, 2023	For the Year Ended December 31, 2022
Audit Fees (1)	$ 85,500	$ 84,000
Audit-Related Fees (2)	—	—
Tax Fees (3)	—	—
All Other Fees (4)	—	—
Total Fees	$ 85,500	$ 84,000

(1) *Audit Fees*. Audit fees consist of fees billed for professional services rendered for the audit of our year-end financial statements, reviews of our quarterly interim financial statements, and services that are normally provided by our independent registered public accounting firm in connection with statutory and regulatory filings. As noted above, we engaged Prager Metis CPAs. LLC to conduct the audit of our financial statements for the years ended December 31, 2023 and 2022.

(2) *Audit-Related Fees*. Audit-related fees consist of fees billed for assurance and related services that are reasonably related to performance of the audit or review of our year-end consolidated financial statements and are not reported under "Audit Fees." These services include attest services that are not required by statute or regulation and consultation concerning financial accounting and reporting standards. We did not pay our independent registered public accounts for other services for the periods shown in the table above.

(3) *Tax Fees*. Tax fees consist of fees billed for professional services relating to tax compliance, tax planning and tax advice. We did not pay our independent registered public accounts for tax services for the periods shown in the table above.

(4) *All Other Fees*. All other fees consist of fees billed for all other services including permitted due diligence services related potential business combinations. We did not pay our independent registered public accounts for other services for the periods shown in the table above.

Auditor Independence

In 2023, there were no other professional services provided by Prager Metis, other than those listed above, that would have required our audit committee to consider their compatibility with maintaining the independence of Prager Metis.

Pre-Approval Policy

The Company's audit committee was formed upon the consummation of the Business Combination. As a result, the audit committee did not pre-approve the 2021 Audit services, although any services rendered prior to the formation of Cardio's audit committee were approved by the Company's board of directors. Since the formation of the audit committee, and on a going-forward basis, the audit committee has and will pre-approve all auditing services and permitted non-audit services to be performed for the Company by its auditors, including the fees and terms thereof (subject to the de minimis exceptions for non-audit services described in the Exchange Act that are approved by the audit committee prior to the completion of the audit).

PART IV

ITEM 15. Exhibits and Financial Statement Schedules

1. Financial Statements

As part of this Annual Report on Form 10-K, the consolidated financial statements are listed in the accompanying Index to Financial Statements on page F-1.

2. Financial Statement Schedules

All schedules are omitted because they are not applicable, or the required information is shown in the Financial Statements or notes thereto.

3. Exhibit Index

The following is a list of exhibits filed as part of this Annual Report on Form 10-K or are incorporated herein by reference:

Exhibit Number	Description	Incorporation by Reference		
		Form	Exhibit	Filing Date
2.1	Agreement and Plan of Merger dated as of May 27, 2022 by and among Mana Capital Acquisition Corp., Mana Merger Sub, Inc., Cardio Diagnostics, Inc., and Meeshanthini (Meesha) Dogan, as representatives of the shareholders (included as Annex A to the Proxy Statement/Prospectus)	8-K	2.1	5/31/22
2.2	Amendment dated September 15, 2022 to Agreement and Plan of Merger dated as of May 27, 2022 by and among Mana Capital Acquisition Corp., Mana Merger Sub, Inc., Cardio Diagnostics, Inc., and Meeshanthini (Meesha) Dogan, as representatives of the shareholders	8-K	2.1	9/15/22
2.3	Waiver Agreement dated as of October 25, 2022 with respect to Agreement and Plan of Merger dated as of May 27, 2022, as amended on September 15, 2022	8-K	2.3	10/31/22
3.1	Third Amended and Restated Certificate of Incorporation of Cardio Diagnostics Holdings, Inc., dated May 30, 2023	8-K	3.1	5/30/23
3.2	By-laws	S-1	3.3	10/19/21
4.1	Specimen Stock Certificate	S-1/A	4.2	11/10/21
4.2	Specimen Warrant Certificate (contained in Exhibit 4.3)	8-K	4.1	11/26/21
4.3	Warrant Agreement, dated November 22, 2021, by and between the Company and Continental Stock Transfer & Trust Company, as warrant agent	8-K	4.1	11/26/21
4.4	Form of Private Placement Warrant	8-K	4.1	2/2/24
4.5*	Description of Securities			
10.1	Form of Non-Competition and Non-Solicitation Agreement	S-4	10.8	5/31/22
10.2#	Form of Board of Directors Agreement, dated June 19, 2023	8-K	10.1	6/22/23
10.3	Registration Rights Agreement, dated November 22, 2021, by and among the Company, the Sponsor and other holders party thereto	8-K	10.4	11/26/21
10.4*#	Cardio Diagnostics Holdings, Inc. 2022 Equity Incentive Plan and related forms of agreements			
10.5#	Form of Indemnification Agreement	S-1	10.5	12/12/22
10.6#	Employment Agreement, executed as of May 27, 2022, between Cardio Diagnostics, Inc. and Meeshanthini Dogan	S-4/A	10.13	8/23/22
10.7#	Employment Agreement, executed as of May 27, 2022, between Cardio Diagnostics, Inc. and Robert Philibert	S-4/A	10.14	8/23/22
10.8#	Employment Agreement, executed as of May 27, 2022, between Cardio Diagnostics, Inc. and Elisa Luqman	S-4/A	10.15	8/23/22
10.9#	Employment Agreement, executed as of May 27, 2022, between Cardio Diagnostics, Inc. and Timur Dogan	S-4/A	10.16	8/23/22
10.10#	Employment Agreement, executed as of May 18, 2022, between Cardio Diagnostics, Inc. and Khullani Abdullahi	S-4/A	10.17	8/23/22
10.11#	Non-Executive Chairman and Consulting Agreement between Cardio Diagnostics, Inc. and Warren Hosseinion	S-4/A	10.18	8/23/22
10.12	Exclusive License Agreement between Cardio Diagnostics, LLC and the University of Iowa Research Foundation dated May 2, 2017	S-4/A	10.11	8/23/22
10.13	First Amendment to Exclusive License Agreement between Cardio Diagnostics, Inc. and the University of Iowa Research Foundation dated September 2, 2022	S-4/A	10.19	9/15/22
10.14§	Lease Agreement, dated July 20, 2023, between the Registrant and 246 Group LC dba North Point Crossing	10-Q	10.1	8/14/23
10.15	Office Building Lease Agreement, dated June 15, 2023, between the Registrant and 311 W. Superior, L.L.C.	10-Q	10.2	8/14/23
10.16	Engagement Letter, dated as of May 13, 2022, between Mana Capital Acquisition Corp. and The Benchmark Company, LLC	10-K	10.18	3/31/23
10.17	Amendment No. 1 to Engagement Letter, dated November 14, 2022, between the Registrant and The Benchmark Company, LLC	10-K	10.19	3/31/23
10.18	At the Market Offering Agreement, dated January 26, 2024, between Cardio Diagnostics Holdings, Inc. and Craig-Hallum Capital Group, LLC	S-3	1.2	1/26/24
21.1*	List of Subsidiaries			
23.1*	Consent of Prager Metis CPA's LLC, independent registered public accounting firm			
24.1*	Power of Attorney(included on signature page of this Form 10-K)			
31.1*	Certification of Principal Executive Officer Pursuant to Exchange Act Rules 13a-14(a) and 15d-14(a), as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002			
31.2*	Certification of Principal Financial Officer Pursuant to Exchange Act Rules 13a-14(a) and 15d-14(a), as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002			
32.1*+	Certification of Principal Executive Officer and Principal Financial Officer pursuant to 18 U.S. C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002			
97*#	Cardio Diagnostics Holdings, Inc. "Clawback" Policy			

101.INS*++	Inline XBRL Instance Document (the instance document does not appear in the Interactive Data File because its XBRL tags are embedded within the Inline XBRL document)
101.SCH*++	XBRL Taxonomy Extension Schema Document.
101.CAL*++	XBRL Taxonomy Extension Calculation Linkbase Document
101.DEF*++	XBRL Taxonomy Extension Definition Linkbase Document
101.LAB*++	XBRL Taxonomy Extension Label Linkbase Document
101.PRE*++	XBRL Taxonomy Extension Presentation Linkbase Document
104*	Cover Page Interactive Date File (embedded with the Inline XBRL document)

* Filed herewith.

\# Indicates a management contract or compensatory plan, contract or arrangement.

§ Certain of the exhibits or schedules to this Exhibit have been omitted in accordance with Regulation S-K Item 601(a)(5). The Registrant agrees to furnish a copy of all omitted exhibits and schedules to the SEC upon its request; provided, however, that the Registrant may request confidential treatment pursuant to Rule 24b-2 of the Exchange Act, as amended, for any schedule or exhibit so furnished.

\+ Furnished herewith. The certifications attached as Exhibit 32.1 that accompanies this Annual Report on Form 10-K is deemed furnished and not filed with the Securities and Exchange Commission and is not to be incorporated by reference into any filing of Cardio Diagnostics Holdings,, Inc. under the Securities Act of 1933, as amended, or the Securities Exchange Act of 1934, as amended, whether made before or after the date of this Annual Report on Form 10-K, irrespective of any general incorporation language contained in such filing.

++ Furnished herewith. Pursuant to Rule 406T of Regulation S-T, the Interactive Data Files on Exhibit 101 hereto are deemed not filed or part of a registration statement or prospectus for purposes of Sections 11 or 12 of the Securities Act of 1933, as amended, are deemed not filed for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, and otherwise are not subject to liability under those sections.

ITEM 16. Form 10-K Summary

None.

SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, the Registrant has duly caused this Report to be signed on its behalf by the undersigned, thereunto duly authorized.

Cardio Diagnostics Holdings, Inc.

Dated: April 1, 2024

By: /s/ Meeshanthini V. Dogan
Meeshanthini V. Dogan
Chief Executive Officer
(Principal Executive Officer)

POWER OF ATTORNEY

Each person whose signature appears below constitutes and appoints Meeshanthini V. Dogan and Elisa Luqman, and each one of them, as her true and lawful attorneys-in-fact and agents, with full power of substitution and resubstitution, for her and in their name, place, and stead, in any and all capacities, to sign any and all amendments to this Annual Report on Form 10-K, and to file the same, with all exhibits thereto and other documents in connection therewith, with the Securities and Exchange Commission, granting unto said attorneys-in-fact and agents, and each of them, full power and authority to do and perform each and every act and thing requisite and necessary to be done in connection therewith, as fully to all intents and purposes as he or she might or could do in person, hereby ratifying and confirming all that said attorneys-in-fact and agents or any of them, or his or her substitute or substitutes, may lawfully do or cause to be done by virtue hereof.

Pursuant to the requirements of the Securities Exchange Act of 1934, this Annual Report on Form 10-K has been signed by the following persons on behalf of the registrant and in the capacities and on the dates indicated.

Signature	**Title and Capacity**	**Date**
/s/ Meeshanthini V. Dogan Meeshanthini V. Dogan, PhD	Chief Executive Officer and Director	April 1, 2024
/s/ Elisa Luqman Elisa Luqman	Chief Financial Officer and Principal Accounting Officer	April 1, 2024
/s/ Warren Hosseinion Warren Hosseinion, MD	Director (Chairman of the Board)	April 1, 2024
/s/ James Intrater James Intrater	Director	April 1, 2024
/s/ Stanley K. Lau Stanley K. Lau	Director	April 1, 2024
/s/ Oded Levy Oded Levy	Director	April 1, 2024
/s/ Robert Philibert Robert Philibert, MD	Director	April 1, 2024

/s/ Paul Burton	Director	April 1, 2024
Paul Burton		

EXHIBIT 4.5

DESCRIPTION OF THE REGISTRANT'S SECURITIES REGISTERED PURSUANT TO SECTION 12 OF THE SECURITIES EXCHANGE ACT OF 1934

The following is a description of the capital stock of Cardio Diagnostics Holdings, Inc. ("Cardio," the "Company," "we," "us," and "our") and certain provisions of our third amended and restated certificate of incorporation (the "certificate of incorporation"), our bylaws (the "bylaws") and the General Corporation Law of the State of Delaware (the "DGCL"), as well as the terms of the warrants issued in our initial public offering (the "public warrants"). This description is summarized from, and qualified in its entirety by reference to, our certificate of incorporation, bylaws, the warrant agreement, dated as of November 22, 2021 (the "Warrant Agreement"), by and between the Company and Continental Stock Transfer & Trust Company, and the applicable provisions of the DGCL. Certain terms used but not otherwise defined herein shall have the meanings ascribed to them in our Annual Report on Form 10-K filed with the Securities and Exchange Commission (the "SEC"), of which this Exhibit 4.5 is a part. The following describes our registered securities as of December 31, 2023. We encourage you to read our certificate of incorporation, our bylaws and the applicable provisions of the DGCL for additional information.

General

The Company has two classes of securities registered under Section 12 of the Securities Exchange Act of 1934, as amended (the "Exchange Act"): (1) common stock; and (2) public warrants. The common stock and public warrants are registered under Section 12 of the Securities Exchange Act of 1934, as amended, and are listed on The Nasdaq Capital Market under the symbols "CDIO" and "CDIOW," respectively.

Our certificate of incorporation currently authorizes the issuance of 300,000,000 shares of common stock, par value $0.00001 and 100,000,000 shares of preferred stock, par value $0.00001 per share. The following description summarizes the material terms of our registered securities.

Common Stock

Voting Rights

Each holder of our common stock is entitled to cast one vote per share. Holders of common stock are not entitled to cumulative voting rights. Except as otherwise required by law or The Nasdaq Stock Market rules (or such other national stock exchange on which are common stock may then by listed), matters to be voted on by stockholders must be approved by the vote of a majority of the votes cast with respect to the matter. Except as otherwise required by the DGCL, our certificate of incorporation or the voting rights granted to the holders of any preferred stock we may subsequently issue, the holders of outstanding shares of common stock and preferred stock entitled to vote thereon, if any, will vote as one class with respect to all matters to be voted on by our stockholders.

Dividend Rights

Each holder of our common stock is entitled to the payment of dividends and other distributions (based on the number of shares of common stock held) as may be declared by our Board of Directors out of our assets or funds legally available for dividends and other distributions. These rights are subject to the preferential rights of the holders of our preferred stock, if any, and any contractual limitations on our ability to declare and pay dividends.

Liquidation, Dissolution and Winding Up

If we are involved in a voluntary or involuntary liquidation, dissolution or winding up of our affairs or a similar event, each holder of our common stock will participate *pro rata* in all assets remaining after payment of liabilities, subject to prior distribution rights of the holders of our preferred stock, if any, then outstanding.

Other Matters

Holders of shares of our common stock do not have subscription, redemption or conversion rights. All outstanding shares of our common stock are validly issued, fully paid and non-assessable.

Holders of our common stock are entitled to one vote for each share held on all matters submitted to a vote of stockholders and do not have cumulative voting rights. An election of directors by our stockholders shall be determined, in an uncontested election, by a majority of the votes cast by the stockholders entitled to vote on the election and, in a contested election, by a plurality of the votes cast by the stockholders entitled to vote on the election. Holders of common stock are entitled to receive proportionately any dividends as may be declared by our board of directors, subject to any preferential dividend rights of any series of preferred stock that we may designate and issue in the future.

Our stockholders have no redemption, preemptive or other subscription rights and there are no sinking fund or redemption provisions applicable to the shares of common stock.

In the event of our liquidation or dissolution, the holders of common stock are entitled to receive an amount of our net assets available for distribution to stockholders after the payment of all debts and other liabilities and subject to the prior rights of any outstanding preferred stock. Holders of common stock have no preemptive, subscription, redemption or conversion rights. Our outstanding shares of common stock are validly issued, fully paid and nonassessable. The rights, preferences and privileges of holders of common stock are subject to and may be adversely affected by the rights of the holders of shares of any series of preferred stock that we may designate and issue in the future.

Public Warrants

Our public warrants are issued under that certain warrant agreement dated November 22, 2021, by and between us and Continental Stock Transfer & Trust Company, as warrant agent. Pursuant to the warrant agreement, each whole public warrant entitles the registered holder to purchase one whole share of our common stock at a price of $11.50 per share, subject to adjustment as discussed below. The public warrants will expire on October 25, 2027, which is five years after completion of our initial business combination, at 5:00 p.m., New York City time, or earlier upon redemption or liquidation.

We will not be obligated to deliver any shares of common stock pursuant to the exercise of a public warrant and will have no obligation to settle such warrant exercise unless a registration statement under the Securities Act with respect to the shares of common stock underlying the warrants is then effective and a prospectus relating thereto is current, subject to our satisfying our obligations described below with respect to registration. No public warrant will be exercisable, and we will not be obligated to issue shares of common stock upon exercise of a public warrant, unless common stock issuable upon such warrant exercise has been registered, qualified or deemed to be exempt under the securities laws of the state of residence of the registered holder of the public warrants. In the event that the conditions in the two immediately preceding sentences are not satisfied with respect to a public warrant, the holder of such warrant will not be entitled to exercise such warrant and such warrant may have no value and expire worthless. In no event will we be required to net cash settle any public warrant.

We filed a registration statement covering the shares of common stock issuable upon exercise of the public warrants, and such registration statement was declared effective on January 24, 2023. As specified in the warrant agreement, we are obligated to maintain a current prospectus relating to those shares of common stock until the warrants expire or are redeemed. During any period when we will have failed to maintain an effective registration statement, warrantholders may exercise public warrants on a "cashless basis" in accordance with Section 3(a)(9) of the Securities Act or another exemption. If that exemption, or another exemption, is not available, holders will not be able to exercise their public warrants on a cashless basis.

We may call the warrants for redemption:

- in whole and not in part;
- at a price of $0.01 per warrant;
- upon not less than 30 days' prior written notice of redemption (the "30-day redemption period") to each warrantholder;

- if, and only if, there is a current registration statement in effect with respect to the shares of common stock underlying such warrants at the time of redemption and for the entire 30-day trading period referred to above and continuing each day thereafter until the date of redemption; and
- if, and only if, the reported last sale price of common stock equals or exceeds $18.00 per share (as adjusted for stock splits, stock dividends, reorganizations, recapitalizations and the like) for any 20 trading days within a 30-trading day period ending three business days before we send the notice of redemption to the warrantholders.

We have established the last of the redemption criteria discussed above to prevent a redemption call unless there is at the time of the call a significant premium to the warrant exercise price. If the foregoing conditions are satisfied, and we issue a notice of redemption of the public warrants, each warrantholder will be entitled to exercise its public warrants prior to the scheduled redemption date. However, the price of common stock may fall below the $18.00 redemption trigger price (as adjusted for stock splits, stock dividends, reorganizations, recapitalizations and the like) as well as the $11.50 warrant exercise price after the redemption notice is issued.

If and when the public warrants become redeemable by us, we may not exercise our redemption right if the issuance of shares of common stock upon exercise of the public warrants is not exempt from registration or qualification under applicable state blue sky laws or we are unable to effect such registration or qualification.

If we call the public warrants for redemption, they may be exercised, for cash or on a "cashless basis" in accordance with the warrant agreement, at the option of a holder, at any time after notice of redemption. The notice of redemption will contain the information necessary to calculate the number of shares of common stock to be received in the event the holder has elected to exercise on a cashless basis. If a record holder has not followed the procedures specified in the notice of redemption and has not surrendered his, her or its public warrant before the redemption date, then on and after the redemption date the holder will have no further rights except to receive, upon surrender of the public warrants, the cash redemption price specified of $0.01.

A holder of a public warrants may notify us in writing in the event it elects to be subject to a requirement that such holder will not have the right to exercise such public warrants, to the extent that after giving effect to such exercise, such person (together with such person's affiliates), to the warrant agent's actual knowledge, would beneficially own in excess of 4.9% or 9.8% (or such other amount as a holder may specify) of the shares of common stock outstanding immediately after giving effect to such exercise.

If the number of outstanding shares of common stock is increased by a stock dividend payable in shares of common stock, or by a split-up of shares of common stock or other similar event, then, on the effective date of such stock dividend, split-up or similar event, the number of shares of common stock issuable on exercise of each public warrant will be increased in proportion to such increase in the outstanding shares of common stock. In addition, if we, at any time while the public warrants are outstanding and unexpired, pay a dividend or make a distribution in cash, securities or other assets to the holders of common stock on account of such shares of common stock (or other shares of our capital stock into which the public warrants are convertible), other than in certain circumstances as described in the warrant agreement, then the warrant exercise price will be decreased, effective immediately after the effective date of such event, by the amount of cash and/or the fair market value of any securities or other assets paid on each share of common stock in respect of such event.

If the number of outstanding shares of our common stock is decreased by a consolidation, combination, reverse stock split or reclassification of shares of common stock or other similar event, then, on the effective date of such consolidation, combination, reverse stock split, reclassification or similar event, the number of shares of common stock issuable on exercise of each public warrant will be decreased in proportion to such decrease in outstanding shares of common stock.

Whenever the number of shares of common stock purchasable upon the exercise of the public warrants is adjusted, as described above, the warrant exercise price will be adjusted by multiplying the warrant exercise price immediately prior to such adjustment by a fraction (x) the numerator of which will be the number of shares of common stock purchasable upon the exercise of the public warrants immediately prior to such adjustment, and (y) the denominator of which will be the number of shares of common stock so purchasable immediately thereafter.

In case of any reclassification or reorganization of the outstanding shares of common stock (other than those described above or that solely affects the par value of such shares of common stock), or in the case of any merger or consolidation of us with or into another corporation (other than a consolidation or merger in which we are the continuing corporation and that does not result in any reclassification or reorganization of our outstanding shares of common stock), or in the case of any sale or conveyance to another corporation or entity of the assets or other property of us as an entirety or substantially as an entirety in connection with which we are dissolved, the holders of the public warrants will thereafter have the right to purchase and receive, upon the basis and upon the terms and conditions specified in the public warrants and in lieu of the shares of our common stock immediately theretofore purchasable and receivable upon the exercise of the rights represented thereby, the kind and amount of shares of stock or other securities or property (including cash) receivable upon such reclassification, reorganization, merger or consolidation, or upon a dissolution following any such sale or transfer, that the holder of the public warrants would have received if such holder had exercised their public warrants immediately prior to such event.

The public warrants have been issued in registered form under the warrant agreement between Continental Stock Transfer & Trust Company, as warrant agent, and us. You should review a copy of the warrant agreement, which is an exhibit to the Annual Report on Form 10-K of which this Exhibit 4.5 is a part, for a complete description of the terms and conditions applicable to the public warrants. The warrant agreement provides that the terms of the public warrants may be amended without the consent of any holder to cure any ambiguity or correct any defective provision, but requires the approval by the holders of at least a majority of the then outstanding public warrants to make any change that adversely affects the interests of the registered holders of public warrants.

The public warrants may be exercised upon surrender of the public warrant certificate on or prior to the expiration date at the offices of the warrant agent, with the exercise form on the reverse side of the warrant certificate completed and executed as indicated, accompanied by full payment of the exercise price (or on a cashless basis, if applicable), by certified or official bank check payable to us, for the number of public warrants being exercised. The warrantholders do not have the rights or privileges of holders of common stock and any voting rights until they exercise their public warrants and receive shares of common stock. After the issuance of shares of common stock upon exercise of the public warrants, each holder will be entitled to one vote for each share held of record on all matters to be voted on by stockholders.

No fractional shares will be issued upon exercise of the public warrants. If, upon exercise of the public warrants, a holder would be entitled to receive a fractional interest in a share, we will, upon exercise, round down to the nearest whole number the number of shares of common stock to be issued to the warrantholder.

Dividends

We have not paid any cash dividends on our shares of common stock to date and do not intend to pay cash dividends prior to the completion of a business combination. The payment of cash dividends in the future will be dependent upon our revenues and earnings, if any, capital requirements and general financial condition subsequent to completion of a business combination. The payment of any dividends subsequent to a business combination will, subject to the laws of the State of Delaware, be within the discretion of our then board of directors. It is the present intention of our board of directors to retain all earnings, if any, for use in our business operations and, accordingly, our board of directors does not anticipate declaring any cash dividends in the foreseeable future. In addition, our board of directors is not currently contemplating and does not anticipate declaring any share dividends in the foreseeable future.

Our Transfer Agent and Warrant Agent

The transfer agent for our common stock and warrant agent for our public warrants is Continental Stock Transfer & Trust Company, 1 State Street Plaza, New York, New York 10004.

Certain Anti-Takeover Provisions of Delaware Law and our Amended and Restated Certificate of Incorporation and By-Laws

We are subject to the provisions of Section 203 of the DGCL regulating corporate takeovers. This statute prevents certain Delaware corporations, under certain circumstances, from engaging in a "business combination" with:

- a stockholder who owns 15% or more of our outstanding voting stock (otherwise known as an "interested stockholder");
- an affiliate of an interested stockholder; or
- an associate of an interested stockholder, for three years following the date that the stockholder became an interested stockholder.

A "business combination" includes a merger or sale of more than 10% of our assets. However, the above provisions of Section 203 do not apply if:

- our board of directors approves the transaction that made the stockholder an "interested stockholder," prior to the date of the transaction;

- after the completion of the transaction that resulted in the stockholder becoming an interested stockholder, that stockholder owned at least 85% of our voting stock outstanding at the time the transaction commenced, other than statutorily excluded shares of common stock; or
- on or subsequent to the date of the transaction, the business combination is approved by our board of directors and authorized at a meeting of our stockholders, and not by written consent, by an affirmative vote of at least two-thirds of the outstanding voting stock not owned by the interested stockholder.

Our authorized but unissued common stock and preferred stock are available for future issuances without stockholder approval and could be utilized for a variety of corporate purposes, including future offerings to raise additional capital, acquisitions and employee benefit plans. The existence of authorized but unissued and unreserved common stock and preferred stock could render more difficult or discourage an attempt to obtain control of us by means of a proxy contest, tender offer, merger or otherwise.

Exclusive Forum for Certain Lawsuits

Our certificate of incorporation requires that, unless the company consents in writing to the selection of an alternative forum, the Court of Chancery of the State of Delaware shall be the sole and exclusive forum for any stockholder (including a beneficial owner) to bring (i) any derivative action or proceeding brought on behalf of the company, (ii) any action asserting a claim of breach of a fiduciary duty owed by any director, officer or other employee of the company to the company or the company's stockholders, (iii) any action asserting a claim against the company, its directors, officers or employees arising pursuant to any provision of the DGCL or our amended and restated certificate of incorporation or the bylaws, or (iv) any action asserting a claim against the company, its directors, officers or employees governed by the internal affairs doctrine, except for, as to each of (i) through (iv) above, (a) any claim as to which the Court of Chancery determines that there is an indispensable party not subject to the jurisdiction of the Court of Chancery (and the indispensable party does not consent to the personal jurisdiction of the Court of Chancery within ten days following such determination), which is vested in the exclusive jurisdiction of a court or forum other than the Court of Chancery, or for which the Court of Chancery does not have subject matter jurisdiction, and (b) any action or claim arising under the Exchange Act or Securities Act of 1933, as amended. This provision may limit a stockholder's ability to bring a claim in a judicial forum that it finds favorable for disputes with the company and its directors, officers, or other employees.

Special Meeting of Stockholders

Our bylaws provide that special meetings of our stockholders may be called only by a majority vote of our board of directors, by our chief executive officer or by our chairman.

Advance Notice Requirements for Stockholder Proposals and Director Nominations; Conduct of Meetings

Our bylaws provide that stockholders seeking to bring business before our annual meeting of stockholders, or to nominate candidates for election as directors at our annual meeting of stockholders must provide timely notice of their intent in writing. To be timely, a stockholder's notice will need to be delivered to our principal executive offices not later than the close of business on the 90th day nor earlier than the opening of business on the 120th day prior to the scheduled date of the annual meeting of stockholders. Our bylaws also specify certain requirements as to the form and content of a stockholders' meeting. These provisions may preclude our stockholders from bringing matters before our annual meeting of stockholders or from making nominations for directors at our annual meeting of stockholders.

Our bylaws allow the chairman of the meeting at a meeting of the stockholders 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 acquirer from conducting a solicitation of proxies to elect the acquirer's own slate of directors or otherwise attempting to influence or obtain control of us.

Exhibit 10.4

CARDIO DIAGNOSTICS HOLDINGS INC.

2022 EQUITY INCENTIVE PLAN

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CARDIO DIAGNOSTICS HOLDINGS INC.

2022 EQUITY INCENTIVE PLAN

SECTION 1 Establishment and Purpose.

(a) **Purpose**. The purpose of the Plan is to promote the interests of Cardio Diagnostics Holdings Inc., a Delaware corporation (the "Company"), and its stockholder providing eligible employees, directors and consultants with additional incentives to remain with the Company and its subsidiaries, to increase their efforts to make the Company more successful, to reward such persons by providing an opportunity to acquire shares of Common Stock on favorable terms and to attract and retain the best available personnel to participate in the ongoing business operations of the Company.

The Plan permits the grant of Incentive Stock Options, Nonstatutory Stock Options, Restricted Stock, Restricted Stock Units, Stock Appreciation Rights, Performance Units and Performance Shares.

(b) **Adoption and Term**. The Plan has been approved by the Board of Directors (the "Board") of the Company, and subject to stockholder approval, and is effect 25, 2022. The Plan will remain in effect until terminated by action of the Board except as otherwise provided in Section 15.

SECTION 2 Definitions.

(a) **"Applicable Laws"** means the requirements relating to the administration of equity-based awards under U.S. state corporate laws, U.S. federal and state secu the Code, any stock exchange or quotation system on which the Common Stock is listed or quoted and the applicable laws of any foreign country or jurisdiction where Awards are, or will be, granted under the Plan.

(b) **"Award"** means the grant of Incentive Stock Options, Nonstatutory Stock Options, Restricted Stock, Restricted Stock Units, Stock Appreciation Rights, Perforr Units or Performance Shares made pursuant to the Plan.

(c) **"Award Agreement"** means an agreement entered into by the Company and the Participant setting forth the terms applicable to an Award granted to the Part under the Plan.

(d) **"Board"** means the Board of Directors of the Company, as constituted from time to time.

(e) **"Cause"** means (i) conviction of, or the entry of a plea of guilty or no contest to, a felony or any other crime that causes the Company public disgrace or disrep adversely affects the Company's operations, condition (financial or otherwise), prospects or interests, (ii) gross negligence or willful misconduct with respect to the Company, including, without limitation fraud, embezzlement, theft or dishonesty in the course of his or her employment; (iii) alcohol abuse or use of controlled drugs other than in accordance with a physician's prescription; (iv) refusal, failure or inability to perform any material obligation or fulfill any duty (other than any duty or obligation of the type described in clause (6) below) to the Company (other than due to a disability), which failure, refusal or inability is not cured within 10 days after delivery of notice thereof; (v) material breach of any agreement with or duty owed to the Company; or (vi) any breach of any obligation or duty to the Company (whether arising by statute, common law, contract or otherwise) relating to confidentiality, noncompetition, nonsolicitation or proprietary rights. Notwithstanding the foregoing, if a Participant and the Company have entered into an employment agreement, consulting agreement or other similar agreement that specifically defines "Cause," then with respect to such Participant, "Cause" shall have the meaning defined in that employment agreement, consulting agreement or other agreement.

(f) **"Change of Control"** means the occurrence of any of the following, in one transaction or a series of related transactions: (i) any person (as such term is used 13(d) and 14(d) of the Exchange Act) becoming a "beneficial owner" (as defined in Rule 13d-3 of the Exchange Act), directly or indirectly, of securities of the Company representing more than 50% of the voting power of the Company's then outstanding capital stock; (ii) a consolidation, share exchange, reorganization or merger of the Company resulting in the stockholders of the Company immediately prior to such event not owning at least a majority of the voting power of the resulting entity's securities outstanding immediately following such event or, if the resulting entity is a direct or indirect subsidiary of the entity whose securities are issued in such transaction(s), the voting power of such issuing entity's securities outstanding immediately following such event; (iii) the sale or other disposition of all or substantially all the assets of the Company (other than a transfer of financial assets made in the ordinary course of business for the purpose of securitization or any similar purpose); (iv) a change in the effective control of the Company which occurs on the date that a majority of members of the Board is replaced during any twelve (12) month period by Directors whose appointment or election is not endorsed by a majority of the members of the Board prior to the date of the appointment or election; (v) a liquidation or dissolution of the Company; or (vi) any similar event deemed by the Committee to constitute a Change in Control for purposes of the Plan. For the avoidance of doubt, a transaction or a series of related transactions will not constitute a Change in Control if such transaction(s) result(s) in the Company, any successor to the Company, or any successor to the Company's business, being controlled, directly or indirectly, by the same person or persons who controlled the Company, directly or indirectly, immediately before such transaction(s).

(g) **"Code"** means the Internal Revenue Code of 1986, as amended.

(h) **"Committee"** means the Compensation Committee of the Board of Directors or such other committee or individuals satisfying Applicable Laws appointed by th accordance with Section 3 hereof.

(i) **"Common Stock"** means the common stock of the Company.

(j) **"Company"** means Cardio Diagnostics Holdings, Inc., a Delaware corporation and where applicable, its Subsidiaries.

(k) **"Consultant"** means any person other than an Employee, engaged by the Company or Subsidiary to render services to such entity.

(l) **"Date of Grant"** means the date on which the Committee grants an Award pursuant to the Plan.

(m) **"Disability"** means total and permanent disability as defined in Section 22(e)(3) of the Code, provided that in the case of Awards other than Incentive Stock O Committee in its discretion may determine whether a permanent and total disability exists in accordance with uniform and non-discriminatory standards adopted by the Committee from time to time.

(n) **"Effective Date"** means October 25, 2022.

(o) **"Employee"** means any individual who is a common-law employee of the Company or a Subsidiary.

(p) **"Exchange Act"** means the Securities Exchange Act of 1934, as amended.

(q) **"Exchange Program"** means a program established by the Committee under which outstanding Awards are amended to provide for a lower Exercise Price or surrendered or cancelled in exchange for (i) Awards with a lower exercise price, (ii) a different type of Award or awards under a different equity incentive plan, (iii) cash, or (iv) a combination of (i), (ii) and/or (iii). Notwithstanding the preceding, the term Exchange Program does not include any (i) action described in Section 12 or any action taken in connection with a Change in Control transaction or (ii) transfer or other disposition permitted under Section 12. For the purpose of clarity, each of the actions described in the prior sentence, none of which constitute an Exchange Program, may be undertaken (or authorized) by the Committee in its sole discretion without approval by the Company's shareholders.

(r) **"Exercise Price"** with respect to an Option, means the price per share at which an Optionee may exercise his Option to acquire all or a portion of the shares o Stock that are the subject of such Option, as determined by the Committee on the Date of Grant. In no event shall the Exercise Price of any Common Stock made the subject of an Option, be less than the Fair Market Value on the Date of Grant.

(s) **"Fair Market Value"** means, as of any date, the value of Common Stock determined as follows:

(i) If the Common Stock is listed on any established stock exchange or a national market system, including without limitation the New York Stock Exchang Global Select Market, the Nasdaq Global Market or the Nasdaq Capital Market of The Nasdaq Stock Market, its Fair Market Value will be the closing sale price for such stock (or the closing bid, if no sales were reported) as quoted on such exchange or system on the day of determination, as reported in *The Wall Street Journal* or such other source as the Committee deems reliable;

(ii) If the Common Stock is regularly quoted by a recognized securities dealer but selling prices are not reported, or if the Common Stock is quoted on the (OTC) market, be that the OTCQB, OTCBB or Pink Sheets, the Fair Market Value of a Share will be the mean between the high bid and low asked prices for the Common Stock on the day of determination, as reported in *The Wall Street Journal*, the OTC, or such other source as the Committee deems reliable;

(iii) For purposes of any Awards granted on the Registration Date, the Fair Market Value will be the initial price to the public as set forth in the final prospec the registration statement in Form S-1 filed with the Securities and Exchange Commission for the initial public offering of the Company's Common Stock; or

(iv) In the absence of an established market for the Common Stock, the Fair Market Value will be determined in good faith by the Board after taking into ac as the Board shall deem appropriate.

(t) **"Incentive Stock Option" or "ISO"** means a stock option intended to satisfy the requirements of Section 422(b) of the Code.

(u) **"Nonstatutory Option"** means a stock option not intended to satisfy the requirements of Section 422(b) of the Code.

(v) **"Officer"** means a person who is an officer of the Company within the meaning of Section 16 of the Exchange Act and the rules and regulations promulgated t

(w) **"Option"** means an ISO or Nonstatutory Option granted under the Plan and entitling the holder to purchase shares of Common Stock.

(x) **"Option Stock"** means those shares of Common Stock made the subject of an Option granted pursuant to the Plan.

(y) **"Optionee"** means an individual who is granted an Option.

(z) **"Outside Director"** means a member of the Board of Directors who is not an Employee.

(aa) **"Participant"** means a person who has an outstanding Award under the Plan. The term Participant also refers to an Optionee.

(bb) **"Performance Goal"** means a performance goal established by the Committee pursuant to Section 10(c) of the Plan.

(cc) **"Performance Share"** means an Award denominated in Shares which may be earned in whole or in part upon attainment of Performance Goals or other vesti as the Committee may determine pursuant to Section 10.

(dd) **"Performance Unit"** means an Award which may be earned in whole or in part upon attainment of Performance Goals or other vesting criteria as the Committ determine and which may be settled for cash, Shares or other securities or a combination of the foregoing pursuant to Section 10.

(ee) **"Plan"** means this Cardio Diagnostics Holdings Inc. 2022 Equity Incentive Plan.

(ff) **"Registration Date"** means the effective date of the first registration statement that is filed by the Company and declared effective pursuant to Section 12(g) o Exchange Act, with respect to any class of the Company's securities.

(gg) **"Repricing"** means (i) reducing the exercise price of Nonqualified Stock Options, Incentive Stock Options, or Stock Appreciation Right (collectively, "Stock Rig cancel outstanding Stock Rights in exchange for cash, other Awards or Options or SARs with an exercise price that is less than the exercise price of the original options or base price of stock appreciation rights, as applicable, (iii) cancel outstanding Stock Rights with an exercise price or base price, as applicable, that is less than the then current Fair Market Value of a Share in exchange for other Awards, cash or other property; or (iv) otherwise effect a transaction that would be considered a "repricing" for purposes of the stockholder approval rules of the applicable securities exchange or inter-dealer quotation system on which the Shares are listed or quoted without stockholder approval.

(hh) **"Restricted Stock"** means those shares of Common Stock made the subject of an Award granted under the Plan.

(ii) **"Restricted Stock Unit"** means a bookkeeping entry representing an amount equal to the Fair Market Value of one Share, granted pursuant to Section 8. Eac Restricted Stock Unit represents an unfunded and unsecured obligation of the Company.

(jj) **"Rule 16b-3"** means Rule 16b-3 of the Exchange Act or any successor to Rule 16b-3, as in effect when discretion is being exercised with respect to the Plan.

(kk) **"Section 16(b)"** means Section 16(b) of the Exchange Act.

(ll) **"Service"** means service as an Employee, Consultant or Outside Director.

(mm) **"Share"** means a share of the Common Stock, as adjusted in accordance with Section 12 of the Plan.

(nn) **"Stock Appreciation Right" or "SAR"** means a right awarded to a Participant pursuant to Section 9 of the Plan, which shall entitle the Participant to receive c Common Stock, other property or a combination thereof, as determined by the Committee, in an amount equal to or otherwise based on the excess of (a) the Fair Market Value of a share of Common Stock at the time of exercise over (b) the exercise price of the right, as established by the Committee on the date the award is granted.

(oo) **"Subsidiary"** means any Company (other than the Company) in an unbroken chain of companies beginning with the Company if each of the companies other last company in the unbroken chain owns stock possessing fifty percent (50%) or more of the total combined voting power of all classes of stock in one of the other companies in such chain. A company that attains the status of a Subsidiary on a date after the adoption of the Plan shall be considered a Subsidiary commencing as of such date.

SECTION 3 Administration.

(a) **Committee of the Board of Directors**. The Plan may be administered by the Compensation Committee of the Board or such other Committee or individuals a by the Board to administer the Plan. Each Committee shall have such authority and be responsible for such functions as the Board has assigned to it. Members of the Committee shall serve for such period of time as the Board may determine and shall be subject to removal by the Board at any time. The Board may also at any time terminate the functions of the Committee and reassume all powers and authorities previously delegated to the Committee. If no Committee has been appointed, the entire Board shall administer the Plan.

To the extent desirable to qualify transactions hereunder as exempt under Rule 16b-3, the transactions contemplated hereunder will be structured to satisfy the requirements for exemption under Rule 16b-3.

(b) **Authority**. Subject to the terms and conditions of the Plan, the Committee shall have the sole discretionary authority:

(i) to authorize the granting of Awards under the Plan;

(ii) to select the Employees, Consultants or Outside Directors who are to be granted Awards under the Plan and to determine the conditions subject to suc

(iii) to construe and interpret the Plan;

(iv) to determine Fair Market Value;

(v) to establish and modify administrative rules for the Plan;

(vi) to impose such conditions and restrictions with respect to the Awards, not inconsistent with the terms of the Plan, as it determines appropriate;

(vii) to execute or cause to be executed Award Agreements; and

(viii) generally, to exercise such power and perform such other acts in connection with the Plan and the Awards, and to make all determinations under the P necessary or advisable or as required, provided or contemplated hereunder.

Any person delegated or designated by the Committee shall be subject to the same obligations and requirements imposed on the Committee and its members under the Plan.

(c) **Exchange Program**. Notwithstanding anything in this Section 3, the Committee shall not implement an Exchange Program without the approval of the holders majority of the Shares that are present in person or by proxy and entitled to vote at any annual or special meeting of Company's shareholders.

(d) **Delegation by the Committee**. The Committee, in its sole discretion and on such terms and conditions as it may provide, may delegate all or any part of its au powers under the Plan to one or more Directors or officers of the Company; provided, however, that the Committee may not delegate its authority and powers (a) with respect to an Officer or (b) in any way which would jeopardize the Plan's qualification under Code Section 162(m), if applicable, or Rule 16b-3.

(e) **Indemnification**. To the maximum extent permitted by law, the Company shall indemnify each member of the Committee, the Board, and any Employee with d under the Plan, against all liabilities and expenses (including any amount paid in settlement or in satisfaction of a judgment) reasonably incurred by the individual in connection with any claims against the individual by reason of the performance of the individual's duties under the Plan. This indemnity shall not apply, however, if: (i) it is determined in the action, lawsuit, or proceeding that the individual is guilty of gross negligence or intentional misconduct in the performance of those duties; or (ii) the individual fails to assist the Company in defending against any such claim. The Company shall have the right to select counsel and to control the prosecution or defense of the suit. The Company shall not be obligated to indemnify any individual for any amount incurred through any settlement or compromise of any action unless the Company consents in writing to the settlement or compromise.

SECTION 4 Eligibility and Award Limitations.

(a) **Award Eligibility**. Employees, Consultants, and Outside Directors shall be eligible for the grant of Awards under the Plan. Only Employees shall be eligible for of Incentive Stock Options.

(b) **Award Limitations**. The Company may apply limits on the grant of Awards during any fiscal year or any particular type or amount of Award.

SECTION 5 Stock Subject To The Plan.

(a) **Shares Subject to the Plan**. The maximum aggregate number of Shares that may be issued under the Plan immediately after the Effective Date is **1,600,000** subject to both increase under Section 5(b) and adjustment under Section 12 after the Effective Date (the "Share Reserve"); provided, however that the Share Reserve will increase on January 1st of each calendar year beginning on **January 1, 2023** and ending on and including January 1, 2027 (each, an "Evergreen Date"), in an amount equal to the lesser of (i) 7% of the total number of shares of Common Stock outstanding on the December 31st immediately preceding the applicable Evergreen Date and (ii) such lesser number of shares of Common Stock as determined to be appropriate by the Committee in its sole discretion. Notwithstanding the foregoing and, subject to adjustment as provided in Section 12, the maximum number of Shares that may be issued upon the exercise of Incentive Stock Options is 1,600,000.

(b) **Lapsed Awards**. To the extent an Award expires, is surrendered pursuant to an Exchange Program or becomes unexercisable without having been exercised respect to Restricted Stock, Restricted Stock Units, Performance Units or Performance Shares, is forfeited to or repurchased by the Company due to failure to vest, the

unpurchased Shares (or for Awards other than Options or Stock Appreciation Rights the forfeited or repurchased Shares), which were subject thereto will become available for future grant or sale under the Plan (unless the Plan has terminated). Notwithstanding the foregoing (and except with respect to Shares of Restricted Stock that are forfeited rather than vested), Shares that have actually been issued under the Plan under any Award will not be returned to the Plan and will not become available for future distribution under the Plan; provided, however, that if Shares issued pursuant to Awards of Restricted Stock, Restricted Stock Units, Performance Shares or Performance Units are repurchased by the Company or are forfeited to the Company, such Shares will become available for future grant under the Plan. Shares used to pay the exercise price of an Award or to satisfy the tax withholding obligations related to an Award will become available for future grant under the Plan. To the extent an Award under the Plan is paid out in cash rather than Shares, such cash payment will not result in reducing the number of Shares available for issuance under the Plan.

SECTION 6 Terms And Conditions Of Stock Options.

(a) **Power to Grant Options**. Subject to the maximum per person share limitation in Section 4, the Committee may grant to such Employees or persons as the Co may select, Options entitling the Optionee to purchase shares of Common Stock from the Company in such quantity, and on such terms and subject to such conditions not inconsistent with the terms of the Plan, as may be established by the Committee at the time of grant or pursuant to applicable resolution of the Committee, and as set forth in the Participant's Option Award Agreement. Options granted under the Plan may be Nonstatutory Stock Options or Incentive Stock Options.

(b) **Optionee to Have No Rights as a Stockholder**. An Optionee, or a transferee of an Optionee, shall have no rights as a stockholder of the Company with respe shares of Common Stock made subject to an Option unless and until such Optionee exercises such Option and is issued the shares purchased thereby. No adjustments shall be made for distributions, dividends, allocations, or other rights with respect to any shares of Common Stock prior to the exercise of such Option.

(c) **Award Agreements**. The terms of any Option shall be set forth in an Award Agreement in such form as the Committee shall from time to time determine. Each Agreement shall comply with and be subject to the terms and conditions of the Plan and such other terms and conditions as the Committee may deem appropriate. In the event that any provision of an Option granted under the Plan shall conflict with any term in the Plan as constituted on the Date of Grant of such Option, the term in the Plan constituted on the Date of Grant of such Option shall control. No person shall have any rights under any Option granted under the Plan unless and until the Company and the Optionee have executed an Award Agreement setting forth the grant and the terms and conditions of the Option.

(d) **Vesting**. Unless a different vesting schedule is listed in an individual Award Agreement, the Shares subject to an Option granted under the Plan shall vest and exercisable in accordance with the following schedule:

Completed Years of Employment/Service From Date of Grant	Cumulative Vesting Percentage
1	25%
2	50%
3	75%
4 Years or more	100%

(e) **Exercise Price and Procedures**.

(1) Exercise Price. The Exercise Price means the price per share at which an Optionee may exercise his Option to acquire all or a portion of the shares of are the subject of such Option. Notwithstanding the foregoing, in no event shall the Exercise Price of any Common Stock made the subject of an Option be less than the Fair Market Value of such Common Stock, determined as of the Date of Grant.

(2) Exercise Procedures. Each Option granted under the Plan shall be exercised by providing written notice to the Committee, together with payment of th which notice and payment must be received by the Committee on or before the earlier of (i) the date such Option expires, and (ii) the last date on which such Option may be exercised as provided in paragraph (f) below.

(3) Payment of Exercise Price. The Exercise Price times the number of the shares to be purchased upon exercise of an Option granted under the Plan sha the time of exercise. The Committee will determine the acceptable form of consideration for exercising an Option, including the method of payment. In the case of an Incentive Stock Option, the Committee will determine the acceptable form of consideration at the time of grant. Such consideration for both types of Options may consist entirely of: (i) cash; (ii) check; (iii) promissory note, to the extent permitted by Applicable Laws, (iv) other Shares, provided that such Shares have a Fair Market Value on the date of surrender equal to the aggregate exercise price of the Shares as to which such Option will be exercised and provided that accepting such Shares will not result in any adverse accounting consequences to the Company, as the Committee determines in its sole discretion; (v) consideration received by the Company under a broker-assisted (or other) cashless exercise program (whether through a broker or otherwise) implemented by the Company in connection with the Plan; (vi) by net exercise; (vii) such other consideration and method of payment for the issuance of Shares to the extent permitted by Applicable Laws; or (viii) any combination of the foregoing methods of payment.

(f) **Effect of Termination of Service**. Subject to paragraph (k) below regarding Special Rules for Incentive Stock Options, the following provisions shall govern th of any Options granted to an Optionee that are vested and outstanding at the time Optionee's Service ceases:

(1) Termination of Employment for Reasons Other than Death, Disability or a Termination for Cause . Should Optionee's Service with the Company cease other than death, Disability or a termination for Cause (as determined by the Committee), then each Option shall remain exercisable until the close of business on the earlier of (i) 3 months following the date Optionee's Service ceased or (ii) the expiration date of the Option.

(2) Termination of Employment Due to Death or Disability . Should Optionee's Service cease due to death or Disability, then each Option shall remain exe close of business on the earlier of (i) the 12 month anniversary of the date Optionee's Service ceased, or (ii) the expiration date of the Option.

(3) Termination for Cause. Should Optionee's Service be terminated for Cause while his Option remains outstanding, each outstanding Option granted to vested or unvested) shall terminate immediately and Optionee shall forfeit all rights with respect to such Award.

(g) **Limited Transferability of Options**. An Option shall be exercisable only by the Optionee during his lifetime and shall not be assignable or transferable other th or by the laws of inheritance following Optionee's death.

(h) **Acceleration of Exercise Vesting**. Notwithstanding anything to the contrary in the Plan, the Committee, in its discretion, may allow the exercise in whole or in any time after the Date of Grant, any Option held by an Optionee, which Option has not previously become exercisable. In the event of a Change of Control of the Company, the Committee, in its discretion may provide that Options shall become 100% vested and exercisable on the date of the Change of Control. Options shall also become 100% vested in the event Optionee dies or becomes Disabled while employed.

(i) **No Repricing**. The terms of any outstanding Award may not be amended, and action may not otherwise be taken, in a manner to achieve a Repricing; provide

that nothing herein shall prevent the Committee from taking any action provided for in Section 14 below

(j) **Modification, Extension, Cancellation and Regrant**. Within the limitations of the Plan and after taking into account any possible adverse tax or accounting consequences, the Committee may modify, or extend outstanding Options or may accept the cancellation of outstanding Options (whether granted by the Company or another issuer) in return for the grant of new Options for the same or a different number of shares and at the same or a different Exercise Price. The foregoing notwithstanding, no modification of an Option shall, without the consent of the Optionee, impair the Optionee's rights or increase the Optionee's obligations under such Option or cause a violation of Code Section 409A.

(k) **Term of Option**. No Option shall have a term in excess of ten (10) years measured from the date that the Option is granted.

(l) **Special Rules For Incentive Stock Options ("ISOs")**. In addition to the provisions of this Section 6, the terms specified below shall be applicable to all Incent Options granted under the Plan. Except as modified by the provisions of this paragraph (k), all of the provisions of the Plan shall be applicable to Incentive Stock Options. Options that are specifically designated as Nonstatutory Options are not subject to the terms of this paragraph (k).

(1) Eligibility. Incentive Options may only be granted to Employees.

(2) Dollar Limitation. The aggregate Fair Market Value of the shares of Common stock (determined as of the Date of Grant) for which one or more Incentiv to any Employee pursuant to the Plan may for the first time become exercisable as Incentive Options during any one calendar year shall not exceed $100,000. To the extent that an Optionee's Options exceed that limit, they will be treated as Nonstatutory Options (but all of the other provisions of the Option shall remain applicable), with the first Options that were awarded to Optionee to be treated as Incentive Stock Options.

(3) Restrictions on Sale of Shares. Shares issued pursuant to the exercise of an Incentive Stock Option may not be sold by the Employee until the expirati after exercise and 24 months from the Date of Grant. Shares that do not satisfy these restrictions shall be treated as a grant of Nonstatutory Options.

(4) Special Rules for Incentive Stock Options Granted to 10% Stockholder .

a. Exercise Price. If any Employee to whom an Incentive Stock Option is granted is a 10% Stockholder, the Exercise Price of the Incentive Stock C 110% of the Fair Market Value of the Company's Common Stock.

b. Term of Option. If any Employee to whom an Incentive Stock Option is granted is a 10% Stockholder, then the Option term shall not exceed five date the Incentive Stock Option is granted.

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c. Definition of 10% Stockholder. For purposes of the Plan, an Employee is deemed to be a "10% Stockholder" if he owns more than 10% of the C

(5) Special Rules for Exercise of Incentive Stock Options Following Termination of Employment .

a. Death or Disability. In order to preserve tax treatment as an Incentive Stock Option, Options granted to an Optionee who dies or becomes Disab be exercised by the Optionee or his executor or beneficiary no later than (i) 12 months following the date of death or Disability, or (ii) the expiration date of the Incentive Stock Option, if earlier.

b. Termination For Reason Other Than Death or Disability . In order to preserve tax treatment as an Incentive Stock Option, an Optionee must exe outstanding Incentive Stock Options no later than: (i) three (3) months following the date the Optionee terminates employment for any reason other than death or Disability; or (ii) the expiration date of the Incentive Stock Option if earlier.

(6) Miscellaneous. With respect to Incentive Stock Options, if this Plan does not contain any provision required to be included herein under Section 422 of provision shall be deemed to be incorporated herein with the same force and effect as if such provision had been set out at length herein. To the extent any Option that is intended to qualify as an Incentive Stock Option cannot so qualify, such Option, to that extent, shall be deemed to be a Nonstatutory Stock Option for all purposes of this Plan.

(m) **Shareholder Rights**. Until the Shares covered by an Option are issued (as evidenced by the appropriate entry on the books of the Company or of a duly autho transfer agent of the Company), no right to vote or receive dividends or any other rights as a stockholder will exist with respect to the Shares subject to an Option, notwithstanding the exercise of the Option. The Company will issue (or cause to be issued) such Shares promptly after the Option is exercised. No adjustment will be made for a dividend or other right for which the record date is prior to the date the Shares are issued, except as provided in Section 12 of the Plan.

SECTION 7 Restricted Stock.

(a) **Grant of Restricted Stock**. The Committee may cause the Company to issue shares of Restricted Stock under the Plan, subject to such restrictions, condition terms as the Committee may determine in addition to those set forth herein.

(b) **Establishment of Performance Criteria and Restrictions**. Restricted Stock Awards will be subject to time vesting under paragraph (f) of this Section 7. The may, in its sole discretion, at the time a grant is made, prescribe restrictions in addition to or other than time vesting, including the satisfaction of corporate or individual performance objectives, which shall be applicable to all or any portion of the Restricted Stock. Corporate or individual performance criteria include, but are not limited to, designated levels or changes in total shareholder return, net income, total asset return, or such other financial measures or performance criteria as the Committee may select. Such restrictions shall be set forth in the Participant's Restricted Stock Agreement.

(c) **Share Certificates and Transfer Restrictions**. Restricted Stock awarded to a Participant may be held under the Participant's name in a book entry account m by or on behalf of the Company. Upon vesting of the Restricted Stock, the Company will establish procedures regarding the delivery of share certificates or the transfer of shares in book entry form. None of the Restricted Stock may be sold, transferred, assigned, pledged or otherwise encumbered or disposed of prior to the date on which such Restricted Stock vests in accordance with the Plan.

(d) **Voting and Dividend Rights**. Except as otherwise determined by the Committee either at the time Restricted Stock is awarded or at any time thereafter prior t of the restrictions, holders of Restricted Stock shall not have the right to vote such shares or the right to receive any dividends with respect to such shares, until such shares are vested. All distributions, if any, received by the Participant with respect to Restricted Stock as a result of any stock split, stock distributions, combination of shares, or other similar transaction shall be subject to the restrictions of the Plan.

(e) **Award Agreements**. The terms of the Restricted Stock granted under the Plan shall be as set forth in an Award Agreement in such form as the Committee sha time to time determine. Each Award Agreement shall comply with and be subject to the terms and conditions of the Plan and such other terms and conditions as the Committee may deem appropriate. No Person shall have any rights under the Plan unless and until the Company and the Participant have executed an Award Agreement setting forth the grant and the terms and conditions of the Restricted Stock. The terms of the Plan shall govern all Restricted Stock granted under the Plan. In the event that any provision of an

Award Agreement shall conflict with any term in the Plan as constituted on the Date of Grant, the term in the Plan shall control.

(f) **Time Vesting**. Except as otherwise provided in a Participant's Award Agreement, the Restricted Stock granted under the Plan will vest in accordance with the f
schedule:

Completed Years of Employment/Service From Date of Grant	Cumulative Vesting Percentage
1	25%
2	50%
3	75%
4 Years or more	100%

In the event a Participant terminates employment prior to 100% vesting, any Shares of Restricted Stock which are not vested shall be forfeited immediately and permanently. However, a Participant shall be 100% vested in his Restricted Stock in the event he terminates employment by reason of death or Disability. A Participant shall also be 100% vested in his Restricted Stock on the date of a Change of Control. If a Participant's Service is terminated for Cause as determined in the sole discretion of the Committee, his or her Restricted Stock Award (whether vested or unvested) shall be forfeited immediately. The Committee may approve Restricted Stock grants that provide alternate vesting schedules. Fractional shares shall be rounded down.

(g) **Acceleration of Vesting**. Notwithstanding anything to the contrary in the Plan, the Board, in its discretion, may accelerate, in whole or in part, the vesting sche
applicable to a grant of Restricted Stock.

SECTION 8 Restricted Stock Units

(a) **Grant**. Restricted Stock Units may be granted at any time and from time to time as determined by the Committee. After the Committee determines that it will gr
Restricted Stock Units under the Plan, it will advise the Participant in an Award Agreement of the terms, conditions, and restrictions (if any) related to the grant, including the number of Restricted Stock Units.

(b) **Vesting Criteria and Other Terms**. The Committee will set vesting criteria in its discretion, which, depending on the extent to which the criteria are met, will de
the number of Restricted Stock Units that will be paid out to the Participant. The Committee may set vesting criteria based upon the achievement of Company-wide, business unit, or individual goals (including, but not limited to, continued employment), or any other basis (including the passage of time) determined by the Committee in its discretion. Unless a different vesting schedule is set forth in the Award Agreement, the following time vesting schedule will apply:

Completed Years of Employment/Service From Date of Grant	Cumulative Vesting Percentage
1	25%
2	50%
3	75%
4 Years or more	100%

(c) **Earning of Restricted Stock Units**. Upon meeting the applicable vesting criteria, the Participant will be entitled to receive a payout as determined by the Com
as set forth in the Award Agreement on the Date of Grant. Notwithstanding the foregoing, at any time after the grant of Restricted Stock Units, the Committee, in its sole discretion, may reduce or waive any vesting criteria that must be met to receive a payout as long as such reduction or waiver does not violate Code Section 409A.

(d) **Dividend Equivalents**. The Committee may, in its sole discretion, award dividend equivalents in connection with the grant of Restricted Stock Units that may b
cash, in Shares of equivalent value, or in some combination thereof.

(e) **Form and Timing of Payment**. Payment of earned Restricted Stock Units will be made upon the date(s) determined by the Committee and set forth in the Awa
Agreement. The Committee, in its sole discretion, may settle earned Restricted Stock Units in cash, Shares, or a combination of both. Timing and payment of Restricted Stock Units will be subject to and structured to comply with the rules of Code Section 409A and the treasury regulations thereunder.

(f) **Cancellation**. On the date set forth in the Award Agreement, all unearned Restricted Stock Units will be forfeited to the Company.

SECTION 9 Stock Appreciation Rights.

(a) **Grant**. A Participant may be granted one or more Stock Appreciation Rights under the Plan and such SARs shall be subject to such terms and conditions, cons
the other provisions of the Plan, as shall be determined by the Committee in its sole discretion. A SAR may relate to a particular Stock Option and may be granted simultaneously with or subsequent to the Stock Option to which it relates. Except to the extent otherwise modified in the grant, (i) SARs not related to a Stock Option shall be granted subject to the same terms and conditions applicable to Stock Options as set forth in Section 6, and (ii) all SARs related to Stock Options granted under the Plan shall be granted subject to the same restrictions and conditions and shall have the same vesting, exercisability, forfeiture and termination provisions as the Stock Options to which they relate. SARs may be subject to additional restrictions and conditions. The per-share base price for exercise or settlement of SARs shall be determined by the Committee but shall be a price that is equal to or greater than the Fair Market Value of such shares. Other than as adjusted pursuant to Section 12, the base price of SARs may not be reduced without shareholder approval (including canceling previously awarded SARs and regranting them with a lower base price).

(b) **Exercise and Payment**. To the extent a SAR relates to a Stock Option, the SAR may be exercised only when the related Stock Option could be exercised and
the Fair Market Value of the shares subject to the Stock Option exceed the exercise price of the Stock Option. When a Participant exercises such SARs, the Stock Options related to such SARs shall automatically be cancelled with respect to an equal number of underlying shares. Unless the Committee decides otherwise (in its sole discretion), SARs shall only be paid in cash or in shares of Common Stock. For purposes of determining the number of shares available under the Plan, each Stock Appreciation Right shall count as one share of Common Stock, without regard to the number of shares, if any, that are issued upon the exercise of the Stock Appreciation Right and upon such payment. Shares issuable in connection with a SAR are subject to the transfer restrictions under the Plan.

SECTION 10 Performance Units and Performance Shares.

(a) **Grant of Performance Units/Shares**. Subject to the terms of the Plan, Performance Units and Performance Shares may be granted to eligible Employees, Co
or Outside Directors at any time and from time to time, as shall be determined by the Committee, in its sole discretion. The Committee shall have complete discretion in determining the number of Performance Units and Performance Shares granted to each Participant.

(b) **Value of Performance Units/Shares**. Each Performance Unit shall have an initial value that is established by the Committee at the time of the grant. Each Pe
Share shall have an initial value equal to the Fair Market Value of a Share on the date of grant. The Committee shall set performance goals in its discretion which, depending on the extent to which they are met, will determine the number and/or value of Performance Units/Shares that will be paid out to the Participants. The time period during which the performance goals must be met shall be called a "Performance Period."

(c) **Performance Objectives and Other Terms**. The Committee will set Performance Goals or other vesting provisions (including, without limitation, continued sta Employee, Consultant or Outside Director) in its discretion which, depending on the extent to which they are met, will determine the number or value of Performance Units/Shares that will be paid out to an Employee, Consultant or Outside Director. The time period during which the performance objectives or other vesting provisions must be met will be called the "Performance Period." Each Award of Performance Units/Shares will be evidenced by an Award Agreement that will specify the Performance Period, and such other terms and conditions as the Committee, in its sole discretion, will determine. The Committee may set performance objectives based upon the achievement of Company-wide, divisional, or individual goals, applicable federal or state securities laws, or any other basis determined by the Committee in its discretion.

(d) **Measurement of Performance Goals**. Performance Goals shall be established by the Committee on the basis of targets to be attained ("Performance Targets respect to one or more measures of business or financial performance (each, a "Performance Measure"), subject to the following:

(i) **Performance Measures**. For each Performance Period, the Committee shall establish and set forth in writing the Performance Measures, if any, and a components and adjustments relating thereto, applicable to each Participant. The Performance Measures, if any, will be objectively measurable and will be based upon the achievement of a specified percentage or level in one or more objectively defined and non-discretionary factors preestablished by the Committee. Performance Measures may be one or more of the following, as determined by the Committee: (i) sales or non-sales revenue; (ii) return on revenues; (iii) operating income; (iv) income or earnings including operating income; (v) net income; (vi) pre-tax income or after-tax income; (vii) net income excluding amortization of intangible assets, depreciation and impairment of goodwill and intangible assets and/or excluding charges attributable to the adoption of new accounting pronouncements; (viii) raising of financing or fundraising; (ix) project financing; (x) revenue backlog; (xi) power purchase agreement backlog; (xii) gross margin; (xiii) operating margin or profit margin; (xiv) capital expenditures, cost targets, reductions and savings and expense management; (xv) return on assets (gross or net), return on investment, return on capital, or return on shareholder equity; (xvi) cash flow, free cash flow, cash flow return on investment (discounted or otherwise), net cash provided by operations, or cash flow in excess of cost of capital; (xvii) performance warranty and/or guarantee claims; (xviii) stock price or total stockholder return; (xix) earnings or book value per share (basic or diluted); (xx) economic value created; (xxi) pre-tax profit or after-tax profit; (xxii) strategic business criteria, consisting of one or more objectives based on meeting specified market penetration or market share, geographic business expansion, objective customer satisfaction or information technology goals; (xxiii) objective goals relating to divestitures, joint ventures, mergers, acquisitions and similar transactions; (xxiv) construction projects consisting of one or more objectives based upon meeting project completion timing milestones, project budget, site acquisition, site development, or site equipment functionality; (xxv) objective goals relating to staff management, results from staff attitude and/or opinion surveys, staff satisfaction scores, staff safety, staff accident and/or injury rates, headcount, performance management, completion of critical staff training initiatives; (xxvi) objective goals relating to projects, including project completion timing milestones, project budget; (xxvii) key regulatory objectives; and (xxviii) enterprise resource planning.

(ii) **Committee Discretion on Performance Measures**. As determined in the discretion of the Committee, the Performance Measures for any Performan differ from Participant to Participant and from Award to Award, (b) be based on the performance of the Company as a whole or the performance of a specific Participant or one or more Subsidiaries, divisions, departments, regions, stores, segments, products, functions or business units of the Company, (c) be measured on a per share, per capita, per unit, per square foot, per employee, per branch basis, and/or other objective basis (d) be measured on a pre-tax or after-tax basis, and (e) be measured on an absolute basis or in relative terms (including, but not limited to, the passage of time and/or against other companies, financial metrics and/or an index). Without limiting the foregoing, the Committee shall adjust any performance criteria, Performance Measures or other feature of an Award that relates to or is wholly or partially based on the number of, or the value of, any stock of the Company, to reflect any stock dividend or split, repurchase, recapitalization, combination, or exchange of shares or other similar changes in such stock.

(e) **Earning of Performance Units/Shares**. After the applicable Performance Period has ended, the holder of Performance Units/Shares shall be entitled to receiv of the number of Performance Unit/Shares earned by the Participant over the Performance Period, to be determined as a function of the extent to which the corresponding Performance Goals have been achieved. Notwithstanding the preceding sentence, after the grant of a Performance Unit/Share, and subject to restrictions under Applicable Laws such as Code Section 409A, the Committee, in its sole discretion, may waive the achievement of any performance goals for such Performance Unit/Share.

(f) **Form and Timing of Payment of Performance Units/Shares**. Payment of earned Performance Units/Shares shall be made in a single lump sum, within 90 c days following the close of the applicable Performance Period. The Committee, in its sole discretion, may pay earned Performance Units/Shares in the form of cash, in Shares (which have an aggregate fair market value equal to the value of the earned Performance Units/Shares at the close of the applicable Performance Period) or in combination thereof. Prior to the beginning of each Performance Period, Participants may, if so permitted by the Company, elect to defer the receipt of any Performance Unit/Share payout upon such terms as the Committee shall determine.

(g) **Cancellation of Performance Units/Shares**. Subject to the applicable Award Agreement, upon the earlier of (a) the Participant's termination of employment, c date set forth in the Award Agreement, all remaining Performance Units/Shares shall be forfeited by the Participant to the Company, the Shares subject thereto shall again be available for grant under the Plan.

(h) **Non-transferability**. Performance Units/Shares may not be sold, transferred, pledged, assigned, or otherwise alienated or hypothecated, other than by will or l of descent and distribution. Further a Participant's rights under the Plan shall be exercisable during the Participant's lifetime only by the Participant or the Participant's legal representative.

SECTION 11 Tax Withholding.

(a) **Tax Withholding for Options**. The Company shall be entitled, if the Committee deems it necessary or desirable, to withhold (or secure payment in cash in Un dollars from an Optionee or beneficiary in lieu of withholding) the amount of any withholding or other tax required by law to be withheld or paid by the Company with respect to any amount payable and/or shares of Common Stock issuable under such Optionee's Option, and the Company may defer payment or issuance of the shares of Common Stock upon such Optionee's exercise of an Option unless indemnified to its satisfaction against any liability for such tax. The amount of any such withholding shall be determined by the Company.

(b) **Tax Withholding for Restricted Stock and Other Awards**. When a Participant incurs tax liability in connection with the vesting, lapse of a restriction or distrit Restricted Stock or other Award, and the Participant is obligated to pay an amount required to be withheld under applicable tax laws, the Committee shall establish procedures to satisfy the withholding tax obligation. The Participant also has the option to make payment in cash in United States dollars pursuant to procedures established by the Company. The amount of any such withholding shall be determined by the Company.

SECTION 12 Adjustment of Shares and Representations.

(a) **General**. Should any change be made to the Common Stock by reason of any stock split, reverse stock split, stock dividend, recapitalization, combination of sh exchange of shares or other change affecting the outstanding Common Stock as a class without the Company's receipt of consideration, the Committee shall make appropriate adjustments to (i) the maximum number and/or class of securities issuable pursuant to the Plan, (ii) the number and/or class of securities and the Exercise Price per share in effect for each outstanding Option in order to prevent the dilution or enlargement of benefits, (iii) the number of shares of Restricted Stock granted; or (iv) the number of Performance Shares awarded, if applicable. As a condition to the exercise of an Award, the Company may require the person exercising such Option to make such representations and warranties at the time of any such exercise as the Company may at that time determine, including without limitation, representations and warranties that (i) the Shares are being purchased only for investment and without any present intention to sell or distribute such Shares in violation of applicable federal or state securities laws, and (ii) such person is

knowledgeable and experienced in financial and business matters and is capable of evaluating the merits and the risks associated with purchasing the Shares.

The inability of the Company to obtain authority from any regulatory body having jurisdiction, which authority is deemed by the Company's counsel to be necessary to the lawful issuance and sale of any Shares under this Plan, shall relieve the Company of any liability in respect of the failure to issue or sell such Shares as to which such requisite authority shall not have been obtained.

(b) **Mergers and Consolidations**. In the event that the Company is a party to a Change of Control, outstanding Awards that are not yet vested shall be subject to agreement of merger or consolidation or asset sale. Such agreement, without the Participant's consent, may provide for:

(i) The continuation of such outstanding Awards by the Company (if the Company is the surviving Company);

(ii) The assumption of the Plan and such outstanding Awards by the surviving Company;

(iii) The substitution by the surviving Company of options with substantially the same terms for such outstanding Awards;

(iv) Such other action as the Board determines.

Each Option that is assumed or otherwise continued in effect in connection with a Change of Control shall be appropriately adjusted, immediately after such Change of Control, to apply to the number and class of securities which would have been issuable to the Optionee in connection with the consummation of such Change of Control, had the Option been exercised immediately prior to such Change of Control.

(c) **Reservation of Rights**. Except as provided in this Section 12, a Participant shall have no Shareholder rights by reason of (i) any subdivision or consolidation o stock of any class, or (ii) any other increase or decrease in the number of shares of stock of any class. Any issuance by the Company of shares of stock of any class, or securities convertible into shares of stock of any class, shall not affect, and no adjustment by reason thereof shall be made with respect to, the number or Exercise Price of shares subject to an Option. The grant of an Option pursuant to the Plan shall not affect in any way the right or power of the Company to make adjustments, reclassifications, reorganizations or changes of its capital or business structure, to merge or consolidate or to dissolve, liquidate, sell or transfer all or any part of its business or assets.

SECTION 13 Miscellaneous.

(a) **Regulatory Approvals**. The implementation of the Plan, the granting of any Options, Restricted Stock or Performance Unit/Performance Share Awards under and the issuance of any shares of Common Stock upon the exercise of any Option, lapse of restrictions on Restricted Stock, or payout of Performance Share Award shall be subject to the Company's procurement of all approvals and permits required by regulatory authorities, if any, including applicable securities laws having jurisdiction over the Plan, the Options or Restricted Stock granted, and the shares of Common Stock issued pursuant to it.

(b) **Strict Construction**. No rule of strict construction shall be implied against the Committee, the Company or Subsidiary or any other person in the interpretation the terms of the Plan, any Award granted under the Plan or any rule or procedure established by the Committee.

(c) **Choice of Law**. All determinations made and actions taken pursuant to the Plan shall be governed by the internal laws of the State of Delaware and construed accordance therewith.

(d) **Compliance With Code Section 409A**. Awards will be designed and operated in such a manner that they are either exempt from the application of, or comply requirements of Code Section 409A such that the grant, payment, settlement or deferral will not be subject to the additional tax or interest applicable under Code Section 409A. The Plan and each Award Agreement under the Plan is intended to meet the requirements of Code Section 409A (or an exemption therefrom) and will be construed and interpreted in accordance with such intent, except as otherwise determined in the sole discretion of the Committee. To the extent that an Award or payment, or the settlement or deferral thereof, is subject to Code Section 409A, the Award will be granted, paid, settled or deferred in a manner that will meet the requirements of Code Section 409A (or an exemption therefrom), such that the grant, payment, settlement or deferral will not be subject to the additional tax or interest applicable under Code Section 409A. In no event will the Company be responsible for or reimburse a Participant for any taxes or other penalties incurred as a result of applicable of Code Section 409A.

(e) **Date of Grant**. The date of grant of an Award will be, for all purposes, the date on which the Committee makes the determination granting such Award, or such date as is determined by the Committee. Notice of the determination will be provided to each Participant within a reasonable time after the date of such grant.

(f) **Conditions Upon Issuance of Shares**.

(i) Legal Compliance. Shares will not be issued pursuant to the exercise of an Award unless the exercise of such Award and the issuance and delivery of comply with Applicable Laws and will be further subject to the approval of counsel for the Company with respect to such compliance.

(ii) Investment Representations. As a condition to the exercise of an Award, the Company may require the person exercising such Award to represent anc of any such exercise that the Shares are being purchased only for investment and without any present intention to sell or distribute such Shares if, in the opinion of counsel for the Company, such a representation is required.

(g) **Clawback Provisions**. All Awards (including the gross amount of any proceeds, gains or other economic benefit the Participant actually or constructively recei receipt or exercise of any Award or the receipt or resale of any Shares underlying the Award) will be subject to recoupment by the Company to the extent required to comply with Applicable Law or any policy of the Company providing for the reimbursement of incentive compensation, whether or not such policy was in place at the time of grant of an Award.

(h) **Stockholder Approval**. The Plan will be subject to approval by the stockholders of the Company within twelve (12) months after the date the Plan is adopted by the Board. Such stockholder approval will be obtained in the manner and to the degree required under Applicable Laws.

SECTION 14 No Employment or Service Retention Rights.

Nothing in the Plan or in any Award granted under the Plan shall confer upon the Participant any right to continue in Service for any period of specific duration or interfere with or otherwise restrict in any way the rights of the Company (or any Subsidiary employing or retaining the Participant) or of the Participant, which rights are hereby expressly reserved by each, to terminate his or her Service at any time and for any reason, with or without cause.

SECTION 15 Duration and Amendments.

(a) **Term of the Plan**. The Plan, as set forth herein, shall become effective on the date of its adoption by the Board, subject to the approval of the Company's stocl the event that the stockholders fail to approve the Plan within 12 months after its adoption by the Board, any grants of Awards that have already occurred for which shareholder approval is a prerequisite for the granting of such Awards, shall be rescinded, and no such additional grants or awards shall be made thereafter under the Plan. The Plan shall terminate upon the earliest to occur of (i) the tenth anniversary of Board approval of the Plan or (ii) the date determined by the Board pursuant to its authority pursuant to paragraph (b) below..

(b) **Right to Amend or Terminate the Plan**. The Plan shall terminate upon the earliest to occur of (i) the tenth anniversary of Board approval of the Plan; (ii) the d

which all Shares available for issuance under the Plan have been issued as fully vested Shares; or (iii) the date determined by the Board pursuant to its authority under Section 12.3 of the Plan.

(c) **Effect of Amendment or Termination**. No amendment, alteration, suspension or termination of the Plan will impair the rights of any Participant, unless mutua otherwise between the Participant and the Committee, which agreement must be in writing and signed by the Participant and the Company. No Shares of Common Stock shall be issued or sold under the Plan after the termination thereof, except upon exercise of an Option granted prior to such termination. The termination of the Plan, or any amendment thereof, shall not affect any shares of Restricted Stock or Performance Shares previously issued or any Option previously granted under the Plan.

SECTION 16 Execution.

To record the adoption of the Plan by the Board of Directors, the Company has caused its authorized officer to execute the same.

CARDIO DIAGNOSTICS HOLDINGS, INC.

By: Elisa Luqman
Elisa Luqman, CFO
Date: October 25, 2022

EXHIBIT 21.1

Subsidiaries of Cardio Diagnostics Holdings, Inc.

Cardio Diagnostics, Inc., a Delaware corporation

Exhibit 23.1

CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

We consent to the incorporation by reference in the Registration Statement on Form S-1 (File No. 333-271147), the Registration Statement on Form S-3 (File No. 333-276725) and the Registration Statement on Form S-8 (File No. 333-270752) of Cardio Diagnostics Holdings, Inc. (the "Company"), of our report dated April 1, 2024, relating to the consolidated financial statements of the Company (which report expresses an unqualified opinion and includes an explanatory paragraph related to the Company's ability to continue as a going concern), appearing in this Annual Report on Form 10-K of the Company for the years ended December 31, 2023 and 2022.

/s/ Prager Metis CPAs, LLC

Hackensack, New Jersey
April 1, 2024

EXHIBIT 31.1

CERTIFICATION OF CHIEF EXECUTIVE OFFICER
PURSUANT TO RULE 13A-14(A) UNDER THE SECURITIES EXCHANGE ACT OF 1934
AS ADOPTED PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Meeshanthini V. Dogan, certify that:

1. I have reviewed this Annual Report on Form 10-K for the year ended December 31, 2023 of Cardio Diagnostics Holdings, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) for the registrant and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under my supervision, to ensure that material information relating to the registrant, is made known to us by others within those entities, particularly during the period in which this report is being prepared; and

b) [Paragraph intentionally omitted in accordance with SEC Release Nos. 34-47986 and 34-54942]; and

c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report my conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: April 1, 2024

Cardio Diagnostics Holdings, Inc.

/s/ Meeshanthini V. Dogan
Meeshanthini V. Dogan
Chief Executive Officer
(Principal Executive Officer)

EXHIBIT 31.2

CERTIFICATION OF CHIEF FINANCIAL OFFICER
PURSUANT TO RULE 13A-14(A) UNDER THE SECURITIES EXCHANGE ACT OF 1934
AS ADOPTED PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Elisa Luqman, certify that:

1. I have reviewed this Annual Report on Form 10-K for the year ended December 31, 2023 of Cardio Diagnostics Holdings, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) for the registrant and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under my supervision, to ensure that material information relating to the registrant, is made known to us by others within those entities, particularly during the period in which this report is being prepared; and

b) [Paragraph intentionally omitted in accordance with SEC Release Nos. 34-47986 and 34-54942]; and

c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report my conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: April 1, 2024

Cardio Diagnostics Holdings, Inc.

/s/ Elisa Luqman
Elisa Luqman
Chief Financial Officer
(Principal Financial Officer)

EXHIBIT 32.1

CERTIFICATION PURSUANT TO
18 U.S.C. SECTION 1350
AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Annual Report on Form 10-K of Cardio Diagnostics Holdings, Inc. (the "Company") for the fiscal year ended December 31, 2023, as filed with the Securities and Exchange Commission (the "Report"), the undersigned officers of the Company certify to such officers' knowledge, pursuant to 18 U.S.C. §1350, as adopted pursuant to §906 of the Sarbanes-Oxley Act of 2002, that:

1. The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

2. The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company as of and for the period covered by the Report.

Dated: April 1, 2024

/s/ Meeshanthini V. Dogan
Meeshanthini V. Dogan
Chief Executive Officer
(Principal Executive Officer)

/s/ Elisa Luqman
Elisa Luqman
Chief Financial Officer
(Principal Financial and Accounting Officer)

Cardio Diagnostics Holdings, Inc.

Compensation Recovery Policy

1. Introduction

The Board of Directors (the "***Board***") of Cardio Diagnostics Holdings, Inc., a corporation organized under the laws of Delaware (the "***Company***"), has adopted this policy (this "***Policy***"), which provides for the recovery of erroneously awarded Incentive-based Compensation (as defined below) from current and former executive officers in the event of an Accounting Restatement (as defined below) resulting from the Company's material noncompliance with any financial reporting requirement under United States federal securities laws. This policy is intended to comply with Section 10D and Rule 10D-1 of the Securities Exchange Act of 1934, as amended (the ***"Exchange Act"***) (***"Rule 10D-1"***), and New Listing Rule 5608 of the Nasdaq Stock Market (the ***"Nasdaq Rule"***). Definitions of capitalized terms used in this Policy are included in Section 11 below.

2. Administration

The Compensation Committee will have full authority to administer this Policy. The Compensation Committee will, subject to the provisions of this Policy, applicable law and regulation, and the Nasdaq Rule, make such determinations and interpretations and take such actions in connection with this Policy as it deems necessary, appropriate or advisable. All determinations and interpretations made by the Compensation Committee will be final, binding and conclusive.

3. Recovery

In the event of an Accounting Restatement, the Company shall seek to recover, reasonably promptly, all Erroneously Awarded Compensation from an Executive Officer during the Time Period Covered in accordance with the Nasdaq Rule and Rule 10D-1. Such determination of the amount of Erroneously Awarded Compensation, in the case of an Accounting Restatement, will be made without regard to any individual knowledge or responsibility related to the Accounting Restatement or the Erroneously Awarded Compensation. Notwithstanding the foregoing, if the Company is required to undertake an Accounting Restatement, the Company shall recover the Erroneously Awarded Compensation unless the recovery is Impracticable (as defined below).

The Company shall seek to recover all Erroneously Awarded Compensation that was awarded or paid in accordance with the definition of "Erroneously Awarded Compensation" set forth below in Section 11. If such Erroneously Awarded Compensation was not awarded or paid on a formulaic basis, the Company shall seek to recover the amount that the Compensation Committee determines in good faith should be recouped.

4. Other Actions

The Compensation Committee may, subject to applicable law, seek recovery in the manner it chooses, including by seeking reimbursement from the Executive Officer of all or part of the compensation awarded or paid, by electing to withhold unpaid compensation, by set-off, or by rescinding or canceling unvested stock.

To the extent that the Executive Officer has already reimbursed the Company for any Erroneously Awarded Compensation received under any duplicative recovery obligations established by the Company or applicable law, it shall be appropriate for any such reimbursed amount to be credited to the amount of Erroneously Awarded Compensation that is subject to recovery under this Policy.

To the extent that an Executive Officer fails to repay all Erroneously Awarded Compensation to the Company when due, the Company shall take all actions reasonable and appropriate to recover such Erroneously Awarded Compensation from the applicable Executive Officer. The applicable Executive Officer shall be required to reimburse the Company for any and all expenses reasonably incurred (including legal fees) by the Company in recovering such Erroneously Awarded Compensation in accordance with the immediately preceding sentence.

In the reasonable exercise of its business judgment under this Policy, the Compensation Committee may in its sole discretion determine whether and to what extent additional action is appropriate to address the circumstances surrounding an Accounting Restatement to minimize the likelihood of any recurrence and to impose such other discipline as it deems appropriate.

5. No Indemnification or Reimbursement

Notwithstanding the terms of any other policy, program, agreement or arrangement, in no event will the Company or any of its affiliates indemnify or reimburse an Executive Officer for any loss of Erroneously Awarded Compensation, or any claims relating to the Company's enforcement of its rights under this Policy and in no event will the Company or any of its affiliates pay premiums on any insurance policy that would cover an Executive Officer's potential obligations with respect to Erroneously Awarded Compensation under this Policy.

6. Other Claims and Rights

The remedies under this Policy are in addition to, and not in lieu of, any legal and equitable claims the Company or any of its affiliates may have or any actions that may be imposed by law enforcement agencies, regulators, administrative bodies, or other authorities. Further, the exercise by the Compensation Committee of any rights pursuant to this Policy will not impact any other rights that the Company or any of its affiliates may have with respect to any Covered Person subject to this Policy.

7. Acknowledgement by Executive Officers; Condition to Eligibility for Incentive Compensation

The Company will provide notice and seek acknowledgement of this Policy from each Executive Officer (see Exhibit A attached hereto), provided that the failure to provide such notice or obtain such acknowledgement will have no impact on the applicability or enforceability of this Policy. After the Effective Date, the Company must be in receipt of an Executive Officer's acknowledgement as a condition to such Executive

Officer's eligibility to receive Incentive-based Compensation. All Incentive-based Compensation subject to this Policy will not be earned, even if already paid, until the Policy ceases to apply to such Incentive-based Compensation and any other vesting conditions applicable to such Incentive Compensation are satisfied.

8. Amendment

The Board may amend this Policy from time to time in its discretion or as it deems necessary. No amendment to this Policy shall be effective if such amendment would (after taking into account any actions taken by the Company contemporaneously with such amendment) cause the Company to violate any federal securities laws, Securities and Exchange Commission rules or Nasdaq Rule.

9. Effectiveness

Except as otherwise determined in writing by the Compensation Committee, this Policy will apply to any Incentive-based Compensation that is Received by an Executive Officer on or after the Effective Date. This Policy will survive and continue notwithstanding any termination of an Executive Officer's employment with the Company and its affiliates.

10. Successors

This Policy shall be binding and enforceable against all Executive Officers and their successors, beneficiaries, heirs, executors, administrators, or other legal representatives.

11. Definitions of Terms

"***Accounting Restatement***" means a restatement of any of the Company's financial statements filed with the Securities and Exchange Commission under the Exchange Act, or the Securities Act of 1933, as amended, due to the Company's material noncompliance with any financial reporting requirement under U.S. securities laws, regardless of whether the Company or Executive Officer misconduct was the cause for such accounting restatement. "Accounting Restatement" includes any accounting restatement the Company is required to prepare to correct an error in previously issued financial statements that is material to the previously issued financial statements, or that would result in a material misstatement if the error were corrected in the current period or left uncorrected in the current period.

"***Compensation Committee***" means the Company's committee comprised entirely of independent directors responsible for executive compensation decisions, or in the absence of such a committee, a majority of the independent directors serving on the Board.

*"**Effective Date**"* means October 2, 2023. Notwithstanding the look-back period under *"Time Period Covered"* below, the Company is only required to apply this Policy to Incentive-based Compensation Received on or after the Effective Date.

"***Erroneously Awarded Compensation***" means the amount of any Incentive-based Compensation (calculated on a pre-tax basis) Received by an Executive Officer during the Time Period Covered that is in excess of the amount that otherwise would have been Received if the calculation were based on the Accounting Restatement. For the avoidance of doubt, Erroneously Awarded Compensation does not include any Incentive-based Compensation Received by a person (i) before such person began service in a position or capacity meeting the definition of an "Executive Officer," (ii) who did not serve as an Executive Officer at any time during the performance period relating to any Incentive-based Compensation, or (iii) during any period the Company did not have a class of its securities listed on a national securities exchange or a national securities association. For Incentive-based Compensation based on (or derived from) stock price or total shareholder return where the amount of Erroneously Awarded Compensation is not subject to mathematical recalculation directly from the information in the applicable Accounting Restatement, the amount will be determined by the Compensation Committee based on a reasonable estimate of the effect of the Accounting Restatement on the stock price or total shareholder return upon which the Incentive-based Compensation was Received (in which case, the Company will maintain documentation of such determination of that reasonable estimate and provide such documentation to the Company's applicable listing exchange).

"***Executive Officer***" means the Company's president, principal financial officer, principal accounting officer (or if there is no such accounting officer, the controller), any vice-president of the issuer in charge of a principal business unit, division, or function (such as sales, administration, or finance), any other officer who performs a policy-making function, or any other person who performs similar policymaking functions for the issuer. Executive officers of an issuer's parent(s) or subsidiaries are deemed executive officers of the issuer if they perform such policy making functions for the issuer. The identification of an executive officer for purposes of this Policy would include at a minimum executive officers identified pursuant to Item 401(b) of Regulation S-K.

"***Financial Reporting Measure***" means a measure that is determined and presented in accordance with the accounting principles used in preparing the Company's financial statements (including "non-GAAP" financial measures, such as those appearing in the Company's earnings releases or Management Discussion and Analysis), and any measure that is derived wholly or in part from such measure. Stock price and total shareholder return (and any measures derived wholly or in part therefrom) shall, for purposes of this Policy, be considered Financial Reporting Measures. For the avoidance of doubt, a Financial Reporting Measure need not be presented in the Company's financial statements or included in a filing with the SEC.

"***Impracticable.***" Either of the following two conditions is met and the Compensation Committee has determined that recovery would be impracticable:

(i) The Compensation Committee has determined that the direct expense paid to a third party to assist in enforcing this Policy would exceed the amount to be recovered after the Company has (A) made a reasonable attempt to recover the Erroneously Awarded Compensation and (B) documented such attempts and provided documentation of such attempts to recover to the Company's applicable listing exchange; or

(ii) Recovery would likely cause an otherwise tax-qualified retirement plan, under which benefits are broadly available to employees of the Company, to fail to meet the qualifications and other applicable requirements of the Internal Revenue Code of 1986, as amended, and regulations thereunder.

"***Incentive-based Compensation***" means any compensation that is granted, earned, or vested based wholly or in part upon the attainment of a Financial Reporting Measure.

"***Received.***" Incentive-based Compensation is deemed "Received" in the Company's fiscal period during which the Financial Reporting Measure specified in the Incentive-based Compensation award is attained, even if the payment or grant of the Incentive-based Compensation occurs after the end of that period.

"***Time Period Covered***" means, with respect to any Accounting Restatement, the three completed fiscal years of the Company immediately preceding the earlier of (i) the date the Board, a committee of the Board, or the officer or officers of the Company authorized to take such action if Board action is not required, concludes (or reasonably should have concluded) that the Company is required to prepare an Accounting Restatement or (ii) the date a regulator, court or other legally authorized entity directs the Company to undertake an Accounting Restatement. The "*Time Period Covered*" also includes any transition period of less than nine months (that results from a change in the Company's fiscal year) within or immediately following the three completed fiscal years identified in the preceding sentence.

Exhibit A

ATTESTATION AND ACKNOWLEDGEMENT OF POLICY FOR THE RECOVERY OF ERRONEOUSLY AWARDED COMPENSATION

By my signature below, I acknowledge and agree that:

- I have received and read the attached Policy for the Recovery of Erroneously Awarded Compensation (this "Policy").

- I hereby agree to abide by all of the terms of this Policy both during and after my employment with the Company, including, without limitation, by promptly repaying or returning any Erroneously Awarded Compensation to the Company as determined in accordance with this Policy.

Signature:

Printed Name:

Date: