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

FORM 10-K

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

For the fiscal year ended December 31, 2022

☐ **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.)

400 North Aberdeen Street, Suite 900
Chicago, IL 60642
(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 whole warrant exercisable for one half of 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 X

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 X

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 X 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 X 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 X	Smaller reporting company X
	Emerging growth company X

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 X

As of June 30, 2022, 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 Global Select Market on June 30, 2022) was approximately $64.5 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 March 27, 2023, there were 9,614,743 shares of common stock, par value $0.00001 issued and outstanding.

Documents Incorporated by Reference: None.

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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 test, or PrecisionCHD™, our recently-introduced test, 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 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;
- the ongoing COVID-19 pandemic has caused a global health crisis that has caused significant economic and social disruption, and its impact on our business is uncertain; 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," that 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 adversely affect our ability realize the anticipated benefits of the Business Combination, and 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 tests, 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 test is performed by a single contract high complexity Clinical Laboratory Improvement Amendments (CLIA) laboratory.
- We may be unable to scale our operations successfully.
- We may be unable to manage our 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 are subject to general litigation that may materially adversely affect us and our operations.

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 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 being a Public Company

- Going public through a merger rather than an underwritten offering presents risks to unaffiliated investors. We may be required to take write-downs or write-offs, restructuring and impairment or other charges that could negatively affect our financial condition, results of operations and stock price, which could cause you to lose some or all of your investment.
- Our management will be required 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.
- We will need to grow the size of our organization and may experience difficulties in managing this growth.

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 nearly 50% 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, and upon conversion of convertible debentures that have been issued or that are expected to be issued upon satisfaction or waiver of applicable conditions, which upon such exercise or conversion 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.
- Insiders will have substantial influence over the Company, which could limit investors' ability to affect the outcome of key transactions, including a change of control.

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.

Background

Mana Capital Acquisition Corp. was formed on May 19, 2021 under the laws of the State of Delaware, as a blank check company for the purpose of engaging in a merger, share exchange, asset acquisition, stock purchase, recapitalization, reorganization or other similar business combination, with one or more target businesses or entities.

On October 25, 2022 (the "Closing"), Cardio Diagnostics Holdings, Inc. (the "Company"), f/k/a Mana Capital Acquisition Corp., our legal predecessor and a special purpose acquisition company ("Mana") sponsored by Mana Capital, LLC, consummated the previously announced Merger with Cardio Diagnostics, Inc. ("Legacy Cardio"), and Mana Merger Sub, Inc. ("Merger Sub"), a wholly owned subsidiary of Mana pursuant to a Merger Agreement and Plan of Reorganization dated as of May 27, 2022, as amended on September 15, 2022 (the "Business Combination Agreement"). Pursuant to the Merger, Merger Sub merged with and into Legacy Cardio, the separate corporate existence of Merger Sub ceased, and Legacy Cardio continued as the surviving corporation in the Merger and as a wholly owned subsidiary of Mana. The Merger was approved by Mana's stockholders at a meeting held on October 25, 2022. On the Closing, the Company changed its name from Mana Capital Acquisition Corp. to Cardio Diagnostics Holdings, Inc.

As of the opening of trading on October 26, 2022, the Company's Common Stock (the "Common Stock") and public warrants (the "Public Warrants"), formerly those of Mana, began trading on The Nasdaq Capital Market ("Nasdaq") under the symbols "CDIO" and "CDIOW," respectively.

At the Closing and subject to the conditions of the Business Combination Agreement, all shares of Common Stock of Legacy Cardio were cancelled and converted into the right to receive a number of shares of the Company's Common Stock equal to 3.427259 (the "Exchange Ratio") per Legacy Cardio share and a pro rata portion of up to 43,334 shares of the Company's Common Stock issuable upon conversion of certain promissory notes aggregating $433,334 issued to Legacy Cardio in consideration of loans made to us to extend the corporate existence of Mana through October 26, 2022 (the "Extension Notes"). In addition, each outstanding option and warrant to purchase shares of Legacy Cardio Common Stock was converted into an option or warrant, as the case may be, to purchase shares of the Company's Common Stock with the same terms except for the number of shares exercisable and the exercise price, as adjusted for the Exchange Ratio.

Our Company

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, early detection and treatment of cardiovascular disease. Cardio is transforming the approach to cardiovascular disease from reactive to proactive and hopes to accelerate the adoption of Precision Medicine for all. We believe that incorporating our 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.

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 as demonstrated by the COVID-19 associated decrease in primary care visits for preventive screening; (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. 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 test targeting CHD events, including heart attacks. In March 2023, we announced the launch of our second product, PrecisionCHD™, an integrated epigenetic-genetic blood test for the early detection of coronary heart disease. The Company earned only $901 and $950 in revenue for the years ended December 31, 2021 and 2022, respectively, through a telemedicine platform. Rather than using its resources to actively pursue this sales channel, in mid to late 2022, we started focusing our efforts on establishing relationships with potential customers, a process that 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 they provide far greater revenue potential for our existing and future tests.

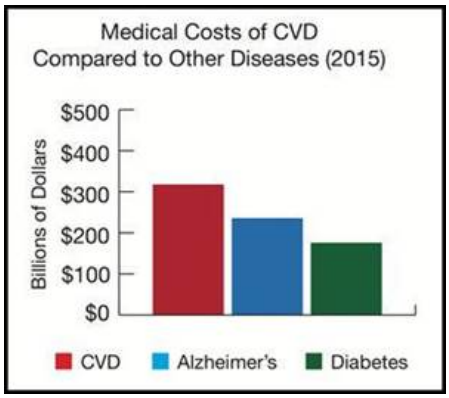
We believe that our Epi+Gen CHD™ and PrecisionCHD™ tests are categorized as laboratory-developed tests, or "LDTs." Under current FDA policy, an LDT does not require premarket authorization or other FDA clearance or approval. As such, we believe that the Epi+Gen CHD™ and PrecisionCHD™ tests do not require FDA premarket evaluation of our performance claims or marketing authorization, and such premarket review and 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.

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.

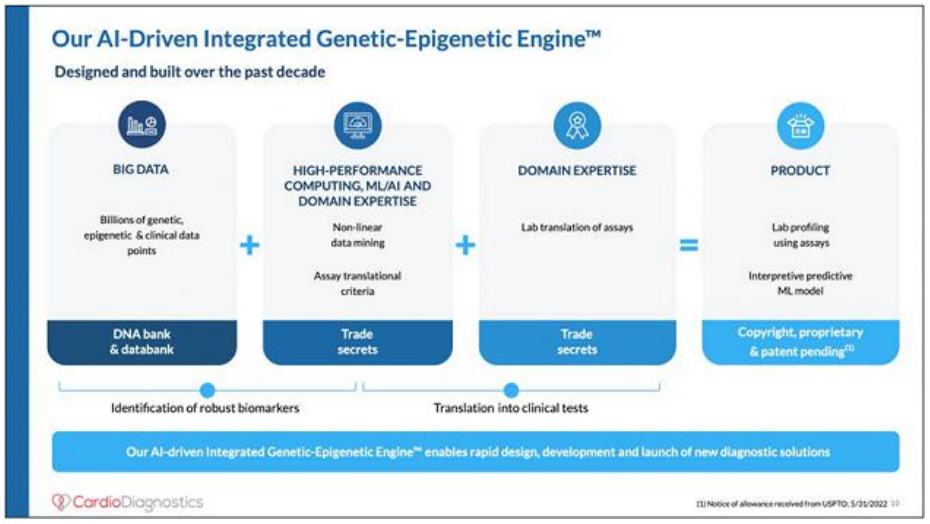
- **Evaluating FDA pathway.** Cardio is evaluating an FDA regulatory pathway to enable broader access to our tests.

- **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.

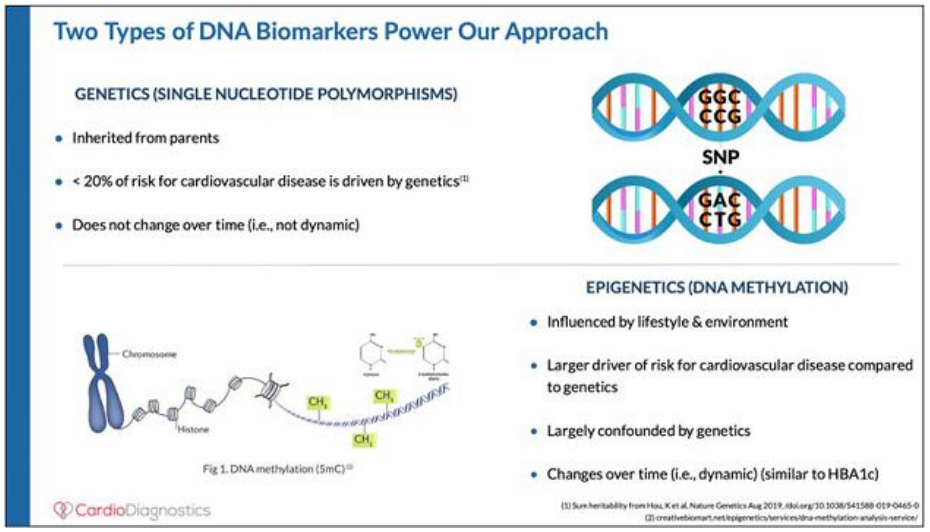
- **Launching synergistic products.** To more fully address cardiovascular health, Cardio is leveraging our AI-driven Integrated Genetic-Epigenetic Engine™ to develop a series of clinical tests for major types of cardiovascular disease and associated co-morbidities, including coronary heart disease, stroke and congestive heart failure.

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.



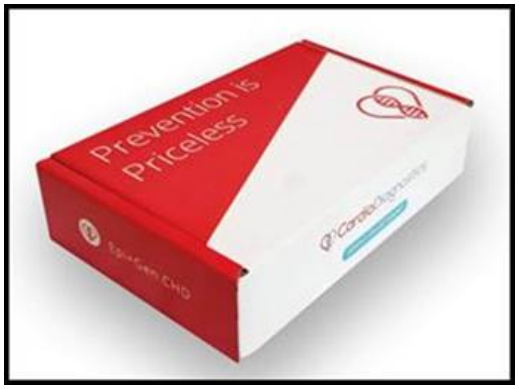
As a result, our products, which are clinical tests, consist of two components. The first is a laboratory component, which involves epigenetic DNA biomarkers. Genetic biomarkers ("SNPs") represent an individual's inherited risk for the disease, have been reported to drive less than 20% of the risk for 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 2023, we have leveraged this Engine to develop two products: Epi+Gen CHD™ and PrecisionCHD™.

We believe that our first product, Epi+Gen CHD™, is the first epigenetics-based clinical 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 test for the early detection of CHD.



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. A similar study was performed for PrecisionCHD™ that demonstrates its high sensitivity and is undergoing the process to be peer-reviewed and published.

- 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.

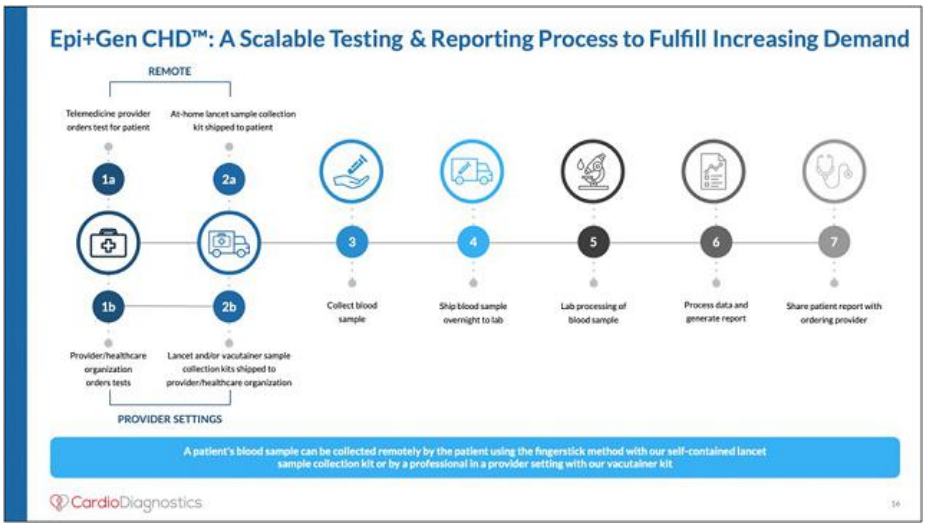
- Lipid-based risk assessment tests depend on self-reported, subjective information such as smoking status from patients, and inaccurate information could affect the accuracy of test results.

- 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 test that is based on an individual's objective genetic and epigenetic DNA biomarkers. 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.



The blood-based version of this test was introduced for market testing in 2021 and the saliva-based version is anticipated to be launching in 2023. The current charge to perform the test is $350, which can be paid for either out-of-pocket or via HSA/FSA. 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. To date, we have sold our Epi+Gen CHD™ test to multiple customers who are patients through a telemedicine provider platform.

We believe that the Epi+Gen CHD™ test empowers patients to prevent CHD with actionable information about their near-term risk for CHD-related events, including a heart attack. We believe that our Company's initial product will enable clinicians to identify patients in need of clinical attention and gaps in cardiovascular care for their patients so they can bridge the gap in care and proactively manage them. In addition, we believe that our products can enable healthcare organizations and payors to reduce the cost of care.

We have a worldwide exclusive license agreement with the University of Iowa Research Foundation ("UIRF") relating to our patent and patent-pending technology. Under the terms of that license agreement, Cardio is required to pay each of: (i) 2% of annual net sales, and (ii) 15% of non-royalty fees paid to the Company if it enters into one or more sublicensing agreements.

In addition to that licensed technology, we have other patent applications pending relating to improvements to and bolstering our technology, which are potentially valuable and of possible strategic importance to the Company. Under UIRF's Inventions Policy, inventors are generally entitled to 25% of income from earnings from their inventions. Consequently, Meeshanthini Dogan and Robert Philibert, our Chief Executive Officer and Chief Medical Officer, who are co-inventors of the technology along with UIRF, will benefit from this policy.

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

PrecisionCHD™ is a scientifically backed clinical test that is based on an individual's objective genetic and epigenetic DNA biomarkers for the early detection of coronary heart disease. PrecisionCHD™ aids in the early detection of coronary heart disease to better enable the management of this condition to prevent a symptomatic event such as a heart attack. Using epigenetic (DNA methylation) and genetic (single nucleotide polymorphism) biomarkers along with a proprietary machine-learning model developed by analyzing billions of genomic and epigenomic data points, PrecisionCHD™ detects coronary heart disease with better than 75% sensitivity in both men and women. A key defining characteristic of PrecisionCHD™ is its accompanying provider-only Actionable Clinical Intelligence™ platform, which maps a patient's unique biomarker profile onto modifiable risk factors such as diabetes, hypertension, hypercholesterolemia, and smoking, known to be critical drivers of coronary heart disease.

Cardio intends to accelerate the adoption of Epi+Gen CHD™ and PrecisionCHD™ by:

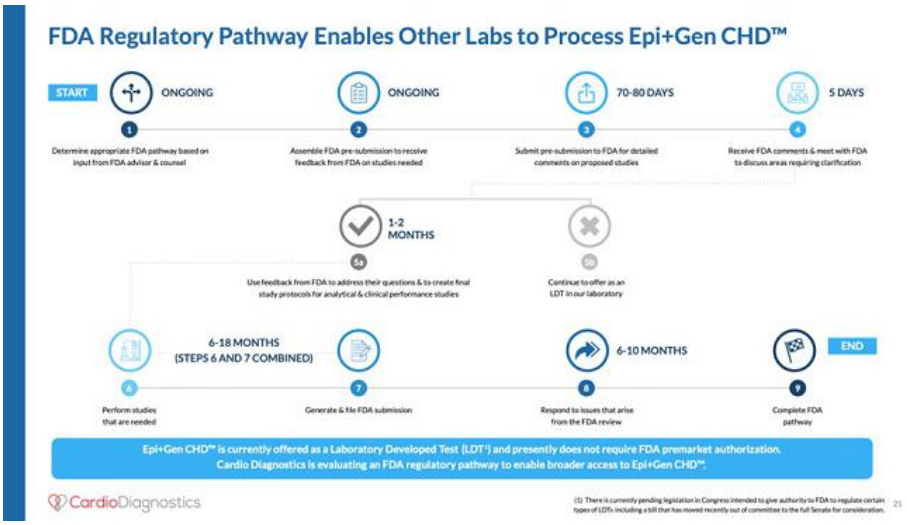
- developing strategic clinical partnerships to reach as many patients as possible;
- leveraging industry organizations to engage and educate providers;
- launching a piloting program to for innovative providers and key strategic partners; and
- developing a customized customer portal to reduce transaction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

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

- acquiring 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 are evaluating an FDA regulatory pathway to enable broader access to the Epi+Gen CHD™ and PrecisionCHD™ tests. We are currently determining the appropriate FDA pathway and are assembling the necessary FDA pre-submission materials to obtain feedback from the FDA. We have engaged regulatory experts and attorneys for this process.



Product Pipeline

In March 2023, we announced the debut of the PrecisionCHD™ test, our second clinical test for the early detection of CHD. In addition to this test, we have several other tests in our product pipeline at various stages for congestive heart failure (expected launch in 2023), stroke (expected launch in 2023) and diabetes (expected launch in 2024).

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 early 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 early 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 assuming $350 per test, the US addressable market equates to $51 billion for Epi+Gen CHD™, $55 billion for PrecisionCHD™, $53 billion for congestive heart failure, $53 billion for stroke and $49 billion for diabetes for a total US addressable market of $261 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™

Since the launch of Epi+Gen CHD™ in 2021 via telemedicine, the predominant initial go-to-market ("GTM") strategy was 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. Our sales and marketing efforts were largely limited due to constraints in resources and predominantly leveraged digital marketing channels. Sales were handled through our telemedicine partner to multiple customers. Moving forward, with additional resources and a growing team, in addition to this bottom-up GTM motion, we have adopted 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.

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 by insurance and eligible for approval for reimbursement. 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 is expected to take several years, if it is obtained at all. We intend to focus on the following key channels:

- 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 early 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 will be driven by remote-first companies looking to provide employee perks relevant to health. We believe the two reasons for this are replacing in-office amenities and acknowledging that health is top of mind for most employees in a post-pandemic world. Health equity is 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 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. Because the Epi+Gen CHD™ test is currently out-of-pocket, we expect high-earning Americans who are proactive about their health to constitute the initial attainable market. Additionally, many have discretionary flexible spending account ("FSA") or health savings account ("HSA") funds. A strategic partner will be health and wellness marketplaces that aggregate FSA and HSA-eligible items for those who wish to tackle their health using their pre-tax dollars. According to the Global Wellness Institute, Americans spend more than $275 billion annually on out-of-pocket wellness and health initiatives.

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™ tests, and bundling our solutions alongside other synergistic technologies, services, and products. We are targeting accelerating the sales cycles for distribution channels for telemedicine, concierge practices, innovative health systems and employers to cycles of four to six weeks, one to nine months, nine to twelve months and six to nine months, respectively.

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 would 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™ 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 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™ tests will be offered as Laboratory Developed Tests ("LDTs") through an experienced laboratory with the appropriate Clinical Laboratory Improvement Amendments of 1988 ("CLIA") certification and state licensure. However, we intend to acquire a laboratory and are currently evaluating potential lab candidates for acquisition.

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.

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 2023, our patent portfolio includes four patent families, one issued U.S. patent, six patent applications pending worldwide, one issued EU patent, one notice of allowance for China, two pending PCT International applications, and one provisional application generally directed to 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, but no competitors of which we are aware use epigenetics.

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 coupled to machine learning 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 three patent families. These patent applications have been filed in the United States and foreign jurisdictions, including the European Union, Japan, Canada and China. In the European Union a patent has already been granted. Recently, a new provisional patent application was filed. 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 is exclusively licensed to Cardio under our license agreement with UIRF. 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. 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, around which there is currently a family of patent and patent applications. 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 the second and third 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 highly associated, at a statistically significant level, 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 2023, this family includes seven granted patents, one soon-to-be issued patent (received notice of allowance), and six 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 includes a granted patent in Europe and the U.S., an allowed application in China and pending applications in Australia, Canada, Europe, India, Japan and the U.S. The issued claims in the EP patent are 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 first SNP in a particular region of the genome (referred to as rs10275666) or another SNP in linkage disequilibrium with the first SNP. The European patent is validated in six European countries including France, Germany, Italy, Ireland, Switzerland, and United Kingdom. The allowed claims in the U.S. are directed to methods for determining the presence of a biomarker associated with coronary heart disease (CHD) that includes performing a genotyping assay on a nucleic acid sample to detect the presence of a SNP in a particular region of the genome (referred to as rs11597065), bisulfite converting a nucleic acid sample and performing a methylation assay to detect the presence or absence of methylation in a particular region of the genome (referred to as cg12586707), and inputting the data from the genotyping assay and the methylation assay into a basic, non-specific algorithm. The original algorithm developed during the initial work is not disclosed in the first family of patents and patent applications. This family of patents is in-licensed under our exclusive license agreement with UIRF and is expected to expire in 2037, absent any applicable patent term adjustments or extensions.

The second family, which is follow-on work conducted by Cardio, is generally directed to a number of SNP biomarkers and a number of methylation site biomarkers that are highly associated, at a statistically significant level, with diabetes. This family includes a pending PCT International application, 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 PCT application also includes 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. The specific algorithm developed for the association of biomarkers with diabetes, which includes an Artificial Intelligence (AI) component, is not a part of the disclosure of the second family of patent applications, and Cardio presently intends to maintain this aspect as a trade secret. Patents issuing from the 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. As of December 2022, this family includes one International PCT application. 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; ownership with UIRF or Cardio, or ownership could be shared between UIRF and us. 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 of patent applications, also considered follow-on work of Cardio, is generally directed to a number of SNP biomarkers and a number of methylation site biomarkers that are highly associated, at a statistically significant level, with the three-year incidence of cardiovascular disease. This family includes one pending PCT International application and a pending U.S. application, 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 PCT application also includes 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. The specific algorithm developed for the association of biomarkers with three-year incidence of cardiovascular disease, which includes an Artificial Intelligence (AI) component, is not a part of the disclosure of the third family of patent applications, and Cardio presently intends to maintain this aspect as a trade secret. This family of patents is owned exclusively by Cardio. As of December 2022, this family includes one International PCT application as well as a one U.S. utility application. Any and all patents issuing in this family will be solely owned by Cardio. Patents issuing from the third family are expected to expire in 2041, 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 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 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 cease to carry on business, or 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 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, trademarks 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 laboratory-developed tests ("LDTs") in particular. As discussed below, legislation has been introduced in Congress that 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.

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."

The laboratory running the test has also been accredited by the College of American Pathologists, or CAP, which means that it has been certified as following CAP standards and guidelines in operating the laboratory facility and in performing tests that ensure the quality of the test results. CAP is a deemed accrediting body for CMS, meaning that successful inspection by CAP satisfies a laboratory's CLIA requirements, and results in the issuance of a Certificate of Accreditation by CMS.

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, or 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, or 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, or 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.

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 a laboratory-developed test, or LDT, to be a test that is developed, validated, used and performed within a single laboratory.

The FDA has historically taken the position that it has the authority to regulate LDTs as in vitro diagnostic, or IVD medical devices under the Federal Food, Drug and Cosmetic Act, or 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. However, there have been situations in which FDA, because of safety, public health, or other concerns, has required companies offering LDTs to comply with FDA regulations applicable to other IVDs, including the requirement for premarket review and authorization.

Separately, the Centers for Medicare and Medicaid Services, or CMS, oversees clinical laboratory operations through the CLIA program.

The regulatory environment for LDTs has changed over time. For example, in 2020, the Department of Health and Human Services, or HHS, directed the FDA to stop regulating LDTs, but in 2021, HHS reversed its policy. Thereafter, the FDA resumed requiring submission of emergency use authorization, or EUA, requests, for COVID-19 LDTs, but has not indicated an intent to change its policy of enforcement discretion with respect to other, non-COVID, LDTs.

Various bills have been introduced in Congress seeking to substantially change the regulation of both LDTs and IVDs:

The VALID Act

In March 2020, the Verifying Accurate Leading-edge IVCT Development, or VALID, Act was introduced in the Senate, and proposed a common regulatory framework for in vitro clinical tests, or IVCTs, which would comprise both IVDs and LDTs, and would require premarket approval for some tests currently offered as LDTs. The VALID Act was reintroduced in June 2021 and would similarly clarify and enhance the FDA's authority to regulate LDTs. The VALID Act was included in the FDA Safety and Landmark Advancements, or FDASLA, legislation, which was favorably voted upon by the Senate Health, Education, Labor and Pensions (HELP) Committee in June 2022. The FDASLA will now be considered by the full Senate. In May 2022, the House Energy and Commerce Committee approved a version of the FDASLA that does not include the VALID Act, and which will now be considered by the full House. If the Senate and the House pass their respective versions of the FDASLA, a Senate-House conference committee will be convened to reconcile the differences in the legislation, including any differences relating to the VALID Act.

If enacted, VALID will foreseeably have a significant impact on the clinical laboratory sector, and many LDTs will be required to undergo FDA premarket review and authorization at some point. The particular impact on our LDTs is difficult to predict at this time. Depending on the final version of the legislation, some tests already on the market as of the date of enactment may be "grandfathered" and may not require premarket authorization, at least initially. Other LDTs may not be required to obtain premarket authorization at all. Additionally, the FDA will need to undertake rulemaking or develop guidance to implement the new law, a process that would likely take months or years. It is therefore not possible to predict the specific impact of VALID on our operations. If premarket authorization is required, it could lead to a substantial increase in the time and cost to bring the tests to market or require significant resources to obtain FDA authorization to allow continued marketing of tests. VALID may also result in ongoing FDA regulatory obligations even for tests that do not need to undergo FDA review.

The VITAL Act

In March 2020, the Verified Innovative Testing in American Laboratories, or VITAL, Act was introduced in the Senate, and would expressly shift the regulation of LDTs from the FDA to CMS. The VITAL Act was reintroduced in May 2021. Unlike the VALID Act, the VITAL Act has not been referred to the HELP Committee and has not been incorporated into FDASLA, making its prospects of enactment in this session of Congress unlikely.

In addition to potential legislation affecting LDTs, the FDA or the Federal Trade Commission, or FTC, as well as state consumer protection agencies and competitors, regulate the materials and methods used in the promotion of LDTs, including with respect to the product claims in promotional materials. Enforcement actions by the FDA, FTC and/or state consumer protection agencies for objectionable claims may include, among others, injunctions, civil penalties, and equitable monetary relief.

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. Although, as mentioned above, the VALID Act was favorably voted upon in June 2022 by the Senate Health, Education, Labor and Pensions Committee as part of the FDA Safety and Landmark Advancements bill, it was not included in the version of that legislation that was enacted by Congress and signed into law. Congress may, through the enactment of other legislation during the current session of Congress or the subsequent Congress, enact VALID or establish new regulatory requirements for LDTs through other legislation.

Regulation by the U.S. Food and Drug Administration

Should the FDA decide not to 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 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, or 510(k), premarket approval, or a PMA, or a de novo authorization.

In vitro diagnostics, or IVDs, are a type of medical device that can be used in the diagnosis or detection of diseases or conditions, including assessment of state of health, through collection, preparation and examination of specimens from the human body. IVDs can be used to detect the presence of certain chemicals, genetic information or other biomarkers related to health or disease. IVDs 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 chosen 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 proposed device is substantially equivalent to a previously 510(k)-cleared device or to 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 previously cleared device is known as a predicate. 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. In addition, the COVID-19 pandemic has resulted in significant workload increases within the Center for Devices and Radiological Health that could affect 510(k) review timelines.

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, including, as noted above, due to delays resulting from the COVID-19 pandemic.

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, performance standards, or other requirements. Subsequent applicants can rely upon the de novo product 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. In October 2021, the FDA issued final regulations codifying FDA's expectations for de novo requests, which went into effect in January 2022. In October 2021, the FDA also issued updated and final guidance on the de novo request and classification process, for the purpose of providing clarity and transparency regarding the de novo classification process. The de novo route has historically been used for many IVD products.

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 products in the field, or removal of products once 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). 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 public warning letter 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.

Corporate Practice of Medicine; Fee-Splitting

We contract with a healthcare telemedicine company to deliver services to our 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 we contract with. Failure to comply with regulations could lead to adverse judicial or administrative action against us and/or the telemedicine 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 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 our 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 March 27, 2023, we had seven full-time employees and one part-time employee. Three of our employees hold Ph.D. or M.D. degrees. We also engage 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, early detection and treatment of cardiovascular disease.

Corporate Information

Mana Capital Acquisition Corp. was formed on May 19, 2021 under the laws of the State of Delaware as a blank check company for the purpose of engaging in a merger, share exchange, asset acquisition, stock purchase, recapitalization, reorganization or other similar business combination, with one or more target businesses or entities. Legacy Cardio was formed in January 2017 as an Iowa limited liability company (Cardio Diagnostics, LLC) and was subsequently incorporated as a Delaware C-Corp (Cardio Diagnostics, Inc.) on September 6, 2019. Upon completion of the Business Combination on October 25, 2022, we changed our name to Cardio Diagnostics Holdings, Inc.

Our corporate headquarters is located at 400 N. Aberdeen St., Suite 900, Chicago IL 60642. 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 400 N. Aberdeen St., Suite 900, Chicago IL 60642.

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 2021 and 2022, including $901 in revenue generated in 2021 and $950 in revenue generated in 2022. Our net losses totaled $620,448 and $4,660,985 for the years ended December 31, 2021 and 2022, respectively, and we have an accumulated deficit of $5,991,541 at December 31, 2022. We expect losses to continue as a result of our ongoing activities to commercially launch our first diagnostic assessment tests, to gain market recognition and acceptance of that initial product, 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 users of our tests through patient awareness as well as through key channel participants;

- gain market acceptance of our initial 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 transitioning to a company capable of supporting commercialization, sales and marketing. We may not be successful in such a transition 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 registration statement 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;
- 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 that use our tests or pricing changes upon any signing and renewals of agreements with healthcare sub-vertical channel participants;
- 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 received less proceeds from the Business Combination than we initially expected. This could prevent us from executing on our business plan and may result in our results of operation and financial condition being worse than we previously projected.

We rely on the availability of capital to grow our business. The projections that we prepared in June 2022 in connection with the Business Combination assumed that we would receive at least an aggregate of $15 million in capital from the Business Combination and the Legacy Cardio private placements conducted in 2022 prior to the Business Combination. This base amount anticipated at least $5.0 million in proceeds remaining in the Trust Account following payment of the requested redemptions. At Closing, we received only a nominal amount of cash from the Trust Account due to higher than expected redemptions by Mana public stockholders and higher than expected expenses in connection with the Business Combination. Accordingly, we have less cash available to pursue our anticipated growth strategies and new initiatives than we projected. This has caused and may continue to cause significant delays in, or limit the scope of, our planned acquisition strategy and our planned product expansion timeline.

Our actual 2022 results differ materially from the projections that were provided for the Business Combination for several reasons, including, among other things: (i) the actual level of redemptions by Mana public stockholders being higher than anticipated redemption levels; (ii) the merger transaction costs and deferred IPO costs substantially exceeding the remainder of the funds in the Trust Account after the redemption amount was paid; and (iii) general and administrative expenses for 2022 are expected to be higher than projected as a result of higher than expected costs associated with investing in growth initiatives and positioning Cardio to operate with a strong corporate governance structure and higher costs related to being a public company, including those related to directors' and officers' liability insurance. As a result of these and other factors, we have earned only $950 in revenue in 2022 compared to the revenue projection of $784,250 included in the projections Legacy Cardio provided to Mana in connection with its consideration of the Business Combination transaction.

Additionally, we currently expect our actual 2023 results to differ materially from our projections for several reasons, including, among other things: (i) the continued and cumulative effects of the factors described in the immediately preceding paragraph, including less than anticipated transaction proceeds and increased costs of revenue; (ii) higher than projected general and administrative expenses as a result of the impact of employee and executive hires and public company expenses, including directors' and officers' liability insurance; and (iii) lower than projected revenues as a result of a having less capital to carry out the business plan on which our projections were based.

Given the dynamic nature of the markets we operate in, and the current status of our business, although we lack the visibility to reasonably quantify, the results for the future periods beyond 2023 may also materially differ from our projections.

Because we experienced high redemptions by Mana public stockholders in connection with the Business Combination and high transaction costs, we have no Trust Account proceeds available to pursue our anticipated growth strategies and new initiatives, including our acquisition strategy, which could have a material impact on our projected estimates and assumptions and actual results of operations and financial condition. The estimates and assumptions used in building our projections required the exercise of judgment and were and continue to be subject to various economic, business, competitive, regulatory, legislative, political and other factors. There can be no assurance that the projected results will be realized even after accounting for the differences discussed herein, or that actual results will not be significantly higher or lower than estimated. Our failure to achieve our projected results could harm the trading price of our securities and our financial position, and adversely affect our future profitability and cash flows.

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

Due to the extremely high percentage of redemptions requested in connection with the Business Combination, substantially all of the funds in the Trust Account that was established as the depository of the IPO net proceeds and proceeds from the private placement sale of the Sponsor Warrants, we expect that we will need additional capital sooner than we previously anticipated. We incurred approximately $2.6 million in transaction costs relating to the Business Combination, consisting of banking, legal and other professional fees, including deferred IPO expenses. After redemptions by public stockholders and payment of such expenses, all funds in the Trust Account at the time of the Business Combination were expended.

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. Based upon our current operating plan, we believe that our existing cash, cash equivalents and restricted cash will be sufficient to fund our operating and capital needs for at least the next 12 months, although we may need to delay the timing of, or scale back, certain aspects of our business plan. This estimate and our expectation regarding the sufficiency of funds 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 medical expense amounts;
- 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 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 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 its solutions, increase adoption and usage of its 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 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 expects, 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 enterprises 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 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 fee 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 Exact Sciences 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.

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. Cardio may in the future experience, disruptions, outages and other performance problems due to a variety of factors, including 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, Cardio or its 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 its solution becomes more complex and its customer 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 Cardio does not effectively address capacity constraints, upgrade its 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™ test, 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 sample collection kits are assembled and fulfilled by one fulfillment center located in Iowa; and the Epi+Gen CHD™ test is performed in one high complexity CLIA laboratory located in Missouri. The reliance on a limited number of suppliers and a sole contract manufacturer, fulfillment center 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 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 its 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 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 Cardio 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 its 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.

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 its ability to maintain a consistently high level of customer service and technical support. Our current and future customers depend on its 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 its 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 and 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™ test 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.

Insiders will continue to have substantial influence over the Company after the Business Combination, which could limit investors' ability to affect the outcome of key transactions, including a change of control.

Following the Business Combination, our executive officers and directors beneficially own approximately 36.7% of our outstanding Common Stock. As a result, these stockholders, if they act together, will be able to influence our management and affairs and most matters requiring stockholder approval, including the election of directors and approval of significant corporate transactions. They may also have interests that differ from other investors and may vote in a way with which other investors disagree and which may be adverse to other investors' interests. This concentration of ownership may have the effect of delaying, preventing or deterring a change in control of our Company and might affect the market price of our Common Stock.

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 new management following the Business Combination 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 toolsets. 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 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 its products and platform. In addition, 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. Further, if a natural disaster, health epidemics or pandemic, 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 its customers or service providers. 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 developed 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, 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, the 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 URIF 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.

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 services and collect reimbursement from governmental programs and private payors, our contractual relationships with our 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 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 the test that we currently offers is a laboratory-developed test, or "LDT." The FDA generally considers an LDT to be a test that is developed, validated and performed within a single laboratory. 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 vitro diagnostic ("IVD") medical device 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.

Moreover, even 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, or 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. The regulatory environment for LDTs has changed over time. For example, in 2020, the Department of Health and Human Services, or HHS, directed the FDA to stop regulating LDTs, but in 2021, HHS reversed its policy. Thereafter, the FDA resumed requiring submission of emergency use authorization, or EUA, requests, for COVID-19 LDTs, but has not indicated an intent to change its policy of enforcement discretion with respect to other, non-COVID, LDTs. Various bills have been introduced in Congress seeking to substantially revamp the regulation of both LDTs and IVDs. For example, the VALID Act, introduced in June 2021, would clarify and enhance the FDA's authority to regulate LDTs, while the VITAL Act, introduced in May 2021, would assign oversight of LDTs exclusively to the Centers for Medicare and Medicaid Services, or CMS.

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. Although the VALID Act was favorably voted upon in June 2022 by the Senate Health, Education, Labor and Pensions Committee as part of the FDA Safety and Landmark Advancements bill, it was not included in the version of that legislation that was enacted by Congress and signed into law. Congress may, through the enactment of other legislation during the current session of Congress or the subsequent Congress, enact VALID or establish new regulatory requirements for LDTs through other legislation.

In the meantime, the regulation by the FDA of LDTs remains uncertain. The FDA may, if Congress does not enact new legislation, seek to establish new requirements for LDTs. 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 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 would be adversely affected while such review is ongoing and if we are ultimately unable to obtain premarket clearance, approval or de novo authorization. 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 plans 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 be used in support of the marketing application. We would also need to submit a premarket notification, or 510(k), a request for de novo authorization, or a PMA application to the FDA and to include information (*e.g.*, clinical and other data) supporting our LDT. Completing such studies requires the expenditure of time, attention and financial and other resources, and may not yield the desired results, which may delay, limit or prevent regulatory clearances, approvals or de novo authorizations. 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.

Certain types of standalone diagnostics software are subject to FDA regulation as a medical device (specifically, software as a medical device or "*SaMD*"). Some types of SaMD are subject to premarket authorization 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 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, which could increase the time and expense involved in implementing such changes commercially. Ongoing compliance with FDA regulations, such as the Quality System Regulation, labeling requirements, Medical Device Reports, and recall reporting, would increase the cost of conducting our business and subject us to heightened regulation by the FDA. 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 and other 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 and competitors, may object to the materials and methods we use to promote the use of our current tests or other LDTs 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, 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 early 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 its 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™ test is 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 client and patient data, including HIPAA-regulated PHI. As a result, our reputation could be severely damaged, adversely affecting client and patient confidence. Members 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 in the amount of at least $2.0 million, 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, and 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 we 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 software 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 software 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 software 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. The severity, magnitude and duration of the current COVID-19 pandemic is uncertain and rapidly changing. As of the date of this Annual Report on Form 10-K, the extent to which the COVID-19 pandemic may impact our business, results of operations and financial condition remains uncertain.

Numerous state and local jurisdictions, have imposed, and others in the future may impose, "shelter-in-place" orders, quarantines, executive orders and similar government orders and restrictions for their residents to control the spread of COVID-19. Such orders or restrictions have resulted in largely remote operations at our place of business, work stoppages among some vendors and suppliers, slowdowns and delays, travel restrictions and cancellation of events, among other effects, thereby significantly and negatively impacting its operations. Other disruptions or potential disruptions include restrictions on the ability of our personnel to travel; inability of its suppliers to manufacture goods and to deliver these to us on a timely basis, or at all; inventory shortages or obsolescence; delays in actions of regulatory bodies; diversion of or limitations on employee resources that would otherwise be focused on the operations of its business, including because of sickness of employees or their families or the desire of employees to avoid contact with groups of people; business adjustments or disruptions of certain third parties; and additional government requirements or other incremental mitigation efforts. The extent to which the COVID-19 pandemic impacts our business will depend on future developments, which are highly uncertain and cannot be predicted, including new information which may emerge concerning the severity and spread of COVID-19 and the actions to contain COVID-19 or treat its impact, among others.

It is not currently possible to reliably project the direct impact of COVID-19 on our operating revenues and expenses. Key factors include the duration and extent of the outbreak in our service areas as well as societal and governmental responses. If the COVID-19 pandemic worsens, especially in regions where we have offices or operations, our business activities originating from affected areas could be adversely affected. Disruptive activities could include business closures in impacted areas, further restrictions on our employees' and service providers' ability to travel, impacts to productivity if our employees or their family members experience health issues, and potential delays in hiring and onboarding of new employees. We may take further actions that alter our business operations as may be required by local, state, or federal authorities or that we determine are in the best interests of our employees. Such measures could negatively affect our sales and marketing efforts, sales cycles, employee productivity, or customer retention, any of which could harm our financial condition and business operations.

The extent and continued impact of the COVID-19 pandemic on our business will depend on certain developments, including: the duration and spread of the outbreak; government responses to the pandemic; the impact on our customers and its sales cycles; the impact on customer, industry, or employee events; and the effect on our partners and supply chains, all of which are uncertain and cannot be predicted. Because of our business model, the full impact of the COVID-19 pandemic may not be fully reflected in our results of operations and overall financial condition until future periods. To the extent the COVID-19 pandemic adversely affects our business and financial results, it may also have the effect of heightening many of the other risks described in this "Risk Factors" section, including but not limited to those relating to cyber-attacks and security vulnerabilities, interruptions or delays due to third-parties, or our ability to raise additional capital or generate sufficient cash flows necessary to expand our operations.

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 2, "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.

The market price of our Common Stock could decline as a result of sales of a large number of shares of Common Stock in the market, or the perception that these sales could occur. There are a total of 9,614,743 shares of Common Stock outstanding as of March 27, 2023. In November 2022, we filed a registration statement on Form S-1 under the Securities Act to register securities, including a primary offering of 3,486,686 shares issuable upon exercise of outstanding warrants and 11,883,256 shares registered for resale by selling stockholders. The SEC declared the registration statement effective on January 24, 2023, and as such, those securities are freely tradeable at any time. In addition, we registered the resale of an additional 236,686 warrants, which if exercised, will also result in freely-tradeable Common Stock. In addition, on March 22, 2023, we filed, and the SEC declared effective, a Form S-8 registration statement covering the Common Stock issuable upon exercise or conversion of stock-based grants and awards issued or issuable under the Company's 2022 Equity Incentive Plan. Upon filing, the shares of Common Stock covered by the Form S-8 the registration statement became eligible for sale in the public market, subject to Rule 144 limitations applicable to affiliates.

In addition, we have agreed, at our expense, to prepare and file registration statements with the SEC providing for the resale of shares of Common Stock issuable upon conversion of convertible debentures (the "YA Convertible Debentures") issued and to be issued to YA II PN, Ltd. ("Yorkville"), a fund managed by Yorkville Advisors Global, LP. We expect to file the first registration statement covering the resale of Yorkville conversion shares soon after filing this Annual Report on Form 10-K. We expect to register for resale up to 20,363,637 shares of Common Stock that are potentially issuable upon conversion of the YA Convertible Debentures. That number assumes conversion at the lowest possible conversion price of $0.55 per share, which we believe is an unlikely outcome but is contractually possible. Yorkville is required to use its commercially reasonable efforts to convert a minimum of at least $1,000,000 of principal amount in the aggregate of its Convertible Debentures per calendar month. In any event, we anticipate that the shares of Common Stock issuable upon conversion of the YA Convertible Debentures will result in a substantial number of shares being held by a single investor who will be free to sell significant blocks of stock, if and when it elects to do so.

Together with our earlier registration statement that was declared effective in January 2023, the S-8 registration statement and the availability of Rule 144 for resales of other securities, virtually all of the shares of Common Stock we have issued in non-public transactions will be eligible to be freely traded in the public market, subject to certain limitations applicable to our affiliates. 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 will be a substantial number of shares registered pursuant to various registration statements, the applicable selling securityholders will 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 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 March 27, 2023, we have Warrants outstanding to purchase 7,854,627 shares of our Common Stock. We will also have the ability to initially issue an aggregate of 3,216,516 shares of our Common Stock under the Cardio Equity Incentive Plan, of which 1,759,599 options have been granted and are currently exercisable. We also have issued $5.0 million of YA Convertible Debentures and expect to issue an additional $6.2 million of YA Convertible Debentures in the second quarter of 2023. The YA Convertible Debentures are convertible at the option of the holder at varying rates depending on the trading price of our Common Stock. The maximum number of shares into which the Debentures could convert is 20,363,637 shares, if the YA Convertible Debentures were converted at the "floor price" of $0.55 per share. We do not expect the conversions to take place at the "floor price" (as defined in the YA Convertible Debentures) of $0.55, although cannot guarantee that our stock price will not, in the future, fall to a level that will result in conversions at the floor price. Upon filing of this Annual Report on Form 10-K, the holder of the First YA Convertible Debenture will be able, but is not required, to convert that debenture into Common Stock, which, if so converted, will result in immediate dilution to existing stockholders.

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.

Our 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.

Warrants to purchase our Common Stock recently became exercisable, which could increase the number of shares eligible for future resale in the public market and result in dilution to our stockholders.

As of the Closing of the Business Combination, there were 7,854,627 Warrants outstanding, all of which are currently exercisable. To the extent Warrants are exercised, 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.

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.

Our management will be required 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.

As a privately held company, Legacy Cardio was not required to comply with certain corporate governance and financial reporting practices and policies required of a publicly traded company. As a publicly traded company, we will incur significant legal, accounting and other expenses that we were not required to incur in the recent past, particularly after we are no longer an "emerging growth company" as defined under the JOBS Act. We are subject to the reporting requirements of the Exchange Act, the Sarbanes-Oxley Act and the rules of the Nasdaq Stock Market. The Sarbanes-Oxley Act requires, among other things, that a company maintain effective disclosure controls and procedures ("DCP") and internal controls over financial reporting ("ICFR"). Our management and other personnel have limited experience operating as a public company, which may result in operational inefficiencies or errors, or a failure to improve or maintain effective ICFR and DCP necessary to ensure timely and accurate reporting of operational and financial results. Our existing management team will need to devote a substantial amount of time to these compliance initiatives and may need to add personnel in areas such as accounting, financial reporting, investor relations and legal in connection with operations as a public company. Ensuring that we have adequate internal financial and accounting controls and procedures in place is a costly and time-consuming effort that needs to be re-evaluated frequently. Our compliance with existing and evolving regulatory requirements will result in increased administrative expenses and a diversion of management's time and attention.

Pursuant to Sections 302 and 404 of the Sarbanes-Oxley Act ("Section 404"), we are required to furnish certain certifications and reports by management on our ICFR, which, after we are no longer an emerging growth company and if we become an accelerated or large accelerated filer under SEC rules, must be accompanied by an attestation report on ICFR issued by our independent registered public accounting firm. To achieve compliance with Section 404 within the prescribed period, we will be required to document and evaluate our ICFR, which is both costly and challenging. Implementing any appropriate changes to our internal controls may require specific compliance training for our directors, officers and employees, entail substantial costs to modify our existing accounting systems, and take a significant period of time to complete. Such changes may not, however, be effective in maintaining the adequacy of our ICFR, and any failure to maintain that adequacy, or consequent inability to produce accurate financial statements on a timely basis, could increase our operating costs and could materially impair our ability to operate our business. Moreover, effective internal controls are necessary for us to produce reliable and timely financial reports and are important to help prevent fraud. Any failure by us to file our periodic reports in a timely manner may cause investors to lose confidence in our reported financial information and may lead to a decline in the price of our Common Stock.

In accordance with The Nasdaq Stock Market rules, the majority of the directors of a company that has securities quoted on Nasdaq must be directors that are "independent" under those rules. The various rules and regulations applicable to public companies make it more difficult and more expensive to maintain directors' and officers' liability insurance, and we may be required to accept reduced coverage or incur substantially higher costs to maintain coverage. If we are unable to maintain adequate directors' and officers' insurance, our ability to recruit and retain qualified officers and directors will be significantly curtailed.

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 it transitions into operating as part of a public company, it expects it will need 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.

If Nasdaq delists our shares or Public Warrants from trading on its exchange 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.

Risks Related to Our Common Stock

The price of our Common Stock likely will be volatile like the stocks of other early-stage companies.

The stock markets in general and the markets for early-stage stocks have experienced extreme volatility. The market for the Common Stock of smaller companies such as ours is characterized by significant price volatility when compared to the shares of larger, more established companies that trade on a national securities exchange and have large public floats, and we expect that our share price will be more volatile than the shares of such larger, more established companies for the indefinite future.

In addition to the factors discussed in this "Risk Factors" section, price declines in our Common Stock could also result from general market and economic conditions and a variety of other factors, including:

- adverse actions taken by regulatory agencies with respect to our products;
- announcements of technological innovations, patents or new products by our competitors;
- regulatory developments in the United States and foreign countries;
- any lawsuit involving us or our product candidates;
- announcements concerning our competitors, or the industry in which we compete in general;
- developments concerning any strategic alliances or acquisitions we may enter into;
- actual or anticipated variations in our operating results;
- changes in recommendations by securities analysts or lack of analyst coverage;
- deviations in our operating results from the estimates of analysts;
- our inability, or the perception by investors that we will be unable, to continue to meet all applicable requirements for continued listing of our Common Stock on the Nasdaq Capital Market, and the possible delisting of our Common Stock;
- sales of our Common Stock by our executive officers, directors and principal stockholders or sales of substantial amounts of Common Stock; and
- loss of any of our key management personnel.

In the past, following periods of volatility in the market price of a particular company's securities, litigation has often been brought against that company. Any such lawsuit could consume resources and Management time and attention, which could adversely affect our business.

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

The trading market for our Common Stock will depend in part on the research and reports that securities or industry analysts publish about us, our business, our market, or our competitors. Securities and industry analysts do not currently, and may never, publish research on the company. Because the Business Combination will result in Cardio being acquired by a special purpose acquisition company ("SPAC"), research coverage from industry analysts may be limited. If no securities or industry analysts commence coverage of our company, our stock price and trading volume could be negatively impacted.

If any of the analysts who may cover the company change their recommendation regarding our stock adversely, provide more favorable relative recommendations about our competitors or publishes inaccurate or unfavorable research about our business, our stock price would likely decline. If any analyst who may cover us ceases coverage of us or fails to publish reports on us regularly, demand for our stock could decrease, which could cause our stock price and trading volume to decline.

Furthermore, if one or more of the analysts who do cover us downgrade our securities stock, its price would likely decline. If one or more of these analysts cease coverage of us, we could lose market visibility, which in turn could cause the price of our securities to decline.

We have broad discretion in the use of our existing cash, cash equivalents and the net proceeds from the Business Combination and may not use them effectively.

Our Management will have broad discretion in the application of our existing cash, cash equivalents and the net proceeds from the Business Combination, and you will not have the opportunity as part of your investment decision to assess whether such proceeds are being used appropriately. Because of the number and variability of factors that will determine our use of our existing cash, cash equivalents and the net proceeds from the Business Combination, their ultimate use may vary substantially from their currently intended use. Our Management might not apply our cash resources in ways that ultimately increase the value of your investment. The failure by our Management to apply these funds effectively could harm our business. Pending their use, we may invest our cash resources in short-term, investment-grade, interest-bearing securities. These investments may not yield a favorable return to our stockholders.

A significant number of shares of our Common Stock are subject to issuance upon exercise of outstanding warrants and options and conversion of Convertible Debentures, which upon such exercise or conversion, as the case may be, may result in dilution to our security holders.

We have outstanding:

- 3,249,993 public warrants, exercisable at a price of $11.50 per share, subject to adjustment and subject to Cardio having an effective registration on file with the SEC which allows for the exercise for cash of the Public Warrants;
- 2,500,000 warrants issued to the Sponsor, exercisable at a price of $11.50 per share, subject to adjustment;
- 1,759,600 Exchanged Options that were issued in exchange for Legacy Cardio options with an exercise price of $3.90 per share, subject to adjustment; and
- 2,204,627 Legacy Cardio Private Placement Warrants that were issued in exchange for outstanding Cardio warrants, with exercise prices ranging between $3.90 and $6.21 per share, subject to adjustment; 100,000 of these warrants were exercised in March 2023.

In March 2023, we issued a Convertible Debenture in the principal amount of $5.0 million and are obligated to issue a second Convertible Debenture in the principal amount of $6.2 million upon satisfaction of certain conditions. These Convertible Debentures may be converted at the option of the holder at varying prices that will depend on the trading price of our Common Stock at the time of conversion. The conversion price could be as low as $0.55, although given current trading prices of our Common Stock, we would expect any conversions to be at prices well above the "Floor Price." Nevertheless, it is possible that conversions of the Convertible Debentures will result in substantial dilution to our securityholders.

To the extent such warrants and options are exercised or debentures converted, additional shares of our Common Stock will be issued, which will result in dilution to the then existing holders of our Common Stock 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 adversely affect the market price of our Common Stock.

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 $3.90 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 $4.25 per share on March 27, 2023. 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.

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.

We have never declared or paid cash dividends on our Common Stock. We do not anticipate paying any cash dividends on our Common Stock in the foreseeable future. We currently intend to retain all available funds and any future earnings to fund the development and growth of our business. As a result, capital appreciation, if any, of our Common Stock will be our stockholders' sole source of gain for 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.

Sales of a substantial number of shares of our Common Stock in the public market or the perception that these sales might occur, could depress the market price of our Common Stock and could impair our ability to raise capital through the sale of additional equity securities. We are unable to predict the effect that sales may have on the prevailing market price of our Common Stock.

Our Second Amended and Restated Certificate of Incorporation designates the Court of Chancery of the State of Delaware as the sole and exclusive forum for certain types of actions and proceedings that may be initiated by the Company's stockholders, which could limit the Company's stockholders' ability to obtain a favorable judicial forum for disputes with the Company or our directors, officers and employees.

Our Second Amended and Restated Certificate of Incorporation will require, unless we consent in writing to the selection of an alternative forum, that (i) any derivative action or proceeding brought on our behalf, (ii) any action asserting a claim of breach of a fiduciary duty owed by any director, officer or other employee to us or our stockholders, (iii) any action asserting a claim against us, our directors, officers or employees arising pursuant to any provision of the DGCL or our Second Amended and Restated Certificate of Incorporation or bylaws, or (iv) any action asserting a claim against us, our directors, officers or employees governed by the internal affairs doctrine may be brought only in the Court of Chancery in the State of Delaware, except any claim (A) as to which the Court of Chancery of the State of Delaware 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), (B) which is vested in the exclusive jurisdiction of a court or forum other than the Court of Chancery, (C) for which the Court of Chancery does not have subject matter jurisdiction, or (D) any action arising under the Securities Act of 1933 or the Securities Exchange Act of 1934. This choice of forum provision may limit a stockholder's ability to bring a claim in a judicial forum that it finds favorable for disputes with the Company or its directors, officers or other employees, which may discourage such lawsuits against the Company and its directors, officers and employees. Alternatively, if a court were to find these provisions of the Second Amended and Restated Certificate of Incorporation inapplicable to, or unenforceable in respect of, 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.

This provision would not apply to any action brought to enforce a duty or liability created by the Exchange Act and inclusive of rules and regulations thereunder. Section 22 of the Securities Act establishes concurrent jurisdiction for federal and state courts over Securities Act claims. Accordingly, both state and federal courts have jurisdiction to hear such claims.

Any person or entity purchasing or otherwise acquiring or holding or owning (or continuing to hold or own) any interest in any of the Company's securities shall be deemed to have notice of and consented to the foregoing bylaw provisions. Although we believe these exclusive forum provisions benefit the Company by providing increased consistency in the application of Delaware law and federal securities laws in the types of lawsuits to which each applies, the exclusive forum provisions may limit a stockholder's ability to bring a claim in a judicial forum of its choosing for disputes with the Company or the Company's current or former directors, officers, stockholders or other employees, which may discourage such lawsuits against the Company and its current and former directors, officers, stockholders and other employees. In addition, a stockholder that is unable to bring a claim in the judicial forum of its choosing may be required to incur additional costs in the pursuit of actions which are subject to the exclusive forum provisions described above. The Company's stockholders will not be deemed to have waived its compliance with the federal securities laws and the rules and regulations thereunder as a result of the Company's exclusive forum provisions.

Further, the enforceability of similar exclusive forum provisions in other companies' organizational documents has been challenged in legal proceedings and it is possible that a court of law could rule that these types of provisions are inapplicable or unenforceable if they are challenged in a proceeding or otherwise. If a court were to find either exclusive forum provision contained in the Company's bylaws to be inapplicable or unenforceable in an action, the Company may incur significant additional costs associated with resolving such action in other jurisdictions, all of which could harm the Company's results of operations.

The Company's anti-takeover provisions could prevent or delay a change in control of the company, even if such change in control would be beneficial to its stockholders.

Provisions of the Company's Second Amended and Restated Certificate of Incorporation and Bylaws, as well as provisions of Delaware law could discourage, delay or prevent a merger, acquisition or other change in control of the Company, even if such change in control would be beneficial to its stockholders. These provisions include:

- the authority to issue "blank check" preferred stock that could be issued by the Board of Directors to increase the number of outstanding shares and thwart a takeover attempt;
- prohibiting the use of cumulative voting for the election of directors;
- requiring all stockholder actions to be taken at a meeting of its stockholders; and
- advance notice requirements for nominations for election to the Board of Directors or for proposing matters that can be acted upon by stockholders at stockholder meetings.

These provisions could also discourage proxy contests and make it more difficult for you and other stockholders to elect directors of your choosing and cause the Company to take other corporate actions you desire. In addition, because the Board of Directors is responsible for appointing the members of our management team, these provisions could in turn affect any attempt by our stockholders to replace current members of our management team.

In addition, the Delaware General Corporation Law (the "DGCL"), to which the post-combination Company is subject, prohibits it, except under specified circumstances, from engaging in any mergers, significant sales of stock or assets or business combinations with any stockholder or group of stockholders who owns at least 15% of its Common Stock.

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.

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.

Item 1B. Unresolved Staff Comments

Not applicable.

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 400 N Aberdeen St, Suite 900, Chicago, Illinois 60642 pursuant to a Membership Agreement. The cost for this space is approximately $8,550 per month with an unaffiliated third party and the third party commencing on May 12, 2022 and is on a twelve month 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. Prior to the consummation of the Business Combination on October 25, 2022, Mana's units, Common Stock, public warrants and rights were listed on the Nasdaq Global Select Market under the symbols "MAAQU," "MAAQ," "MAAQW" and "MAAQR," respectively. There was no public trading market for Legacy Cardio's equity.

Holders

As of March 27, 2023, there were 91 holders of record of our common stock and ten 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

At March 27, 2022, there were 7,854,620 warrants outstanding for the purchase of Company Common Stock. Refer to Note7 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

None.

Issuer Purchases of Equity Securities

None.

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, 2022 and 2021 and for each of the two years in the period ended December 31, 2022 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 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's ongoing strategy for expanding its business operations includes the following:

- Develop blood-based and saliva-based products for stroke, congestive heart failure and diabetes;
- Build out clinical and health economics evidence in order to obtain payer reimbursement for Cardio's tests;
- Expand its testing process outside of a single high complexity CLIA laboratory to multiple laboratories, including hospital laboratories;
- Introduce the test across several additional key channels, including health systems and self-insured employers; and
- Pursue the potential acquisition of one or more laboratories and/or synergistic companies in the telemedicine, AI or remote patient monitoring space.

Recent Developments

The Business Combination

On October 25, 2022, we consummated the Business Combination. Pursuant to the Business Combination Agreement, Merger Sub merged with and into Legacy Cardio, with Legacy Cardio surviving the merger and becoming a wholly-owned direct subsidiary of Mana. Thereafter, Merger Sub ceased to exist, and Mana was renamed Cardio Diagnostics Holdings, Inc.

The Business Combination was accounted for as a reverse recapitalization, in accordance with GAAP. Under the guidance in ASC 805, Mana was treated as the "acquired" company for financial reporting purposes. Legacy Cardio was deemed the accounting predecessor of the combined business, and Cardio Diagnostics Holdings, Inc., as the parent company of the combined business, was the successor SEC registrant, meaning that our financial statements for previous periods will be disclosed in the registrant's periodic reports filed with the SEC.

The Business Combination had a significant impact on the Company's reported financial position and results as a consequence of the reverse recapitalization. As noted in Note 1 to the Company's consolidated financial statements, the Company's financial position reflects current liabilities that include existing, deferred liabilities originally incurred by Mana that are payable by the Company to Ladenburg Thalmann & Co., Inc. ("Ladenburg") and I-Bankers Securities, Inc. ("I-Bankers"), the underwriters of Mana's initial public offering, and The Benchmark Company, LLC ("Benchmark"), the M&A advisor Mana retained in connection with the Business Combination. The aggregate amount of the liabilities owed to these investment bankers, as assumed by the Company in connection with the Business Combination, totals $928,500. This sum reflects a decrease in the amount of the original liabilities incurred by Mana, including a 30% decrease in the liability owed to Ladenburg and I-Bankers and a 46% decrease in the original liability incurred by Mana to Benchmark. The $928,500 is due and payable to the investment bankers on October 25, 2023. However, on March 25, 2023, Ladenburg offered us a 15% early pay discount on the balance due. On March 27, 2023, we accepted the early pay discount and paid Ladenburg the net balance due and payable of $419,475. The balance of $435,000 owed to Benchmark remains due and payable on October 25, 2023.

In addition, the Company acquired only $4,021 in cash after the payment of transaction costs and outstanding accounts payable, primarily as a result of a redemption rate of over 99% by the holders of Mana's publicly-traded Common Stock, which shares had a redemption right in connection with the Business Combination. Specifically, Mana's public 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, Legacy Cardio's 1,976,749 issued and outstanding common shares were reversed, and the Mana common shares totaling 9,514,743 were recorded, as described in Note 7. 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.

As an SEC-registered and Nasdaq-listed company, post-merger, the Company will need to hire additional personnel and implement procedures and processes to address public company regulatory requirements and customary practices. The Company expects to incur additional annual expenses as a public company for, among other things, directors' and officers' liability insurance, director fees, and additional internal and external accounting, legal and administrative resources.

COVID-19 Impact

The global COVID-19 pandemic continues to evolve. The extent of the impact of the COVID-19 pandemic on Cardio's business, operations and development timelines and plans remains uncertain and will depend on certain developments, including the duration and spread of the outbreak and its impact on Cardio's development activities, third-party manufacturers, and other third parties with whom Cardio does business, as well as its impact on regulatory authorities and Cardio's key scientific and management personnel.

The ultimate impact of the COVID-19 pandemic is highly uncertain and subject to change. To the extent possible, Cardio is conducting business as usual, with necessary or advisable modifications to employee travel and with certain of its employees working remotely all or part of the time. Cardio will continue to actively monitor the evolving situation related to COVID-19 and may take further actions that alter our operations, including those that federal, state or local authorities may require, or that we determine in the best interests of our employees and other third parties with whom we do business. At this point, the extent to which the COVID-19pandemic may affect our future business, operations and development timelines and plans, including the resulting impact on Cardio's expenditures and capital needs, remains uncertain.

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, 2022 and 2021:

	Years Ended December 31,	
	2022	2021
Revenue		
Revenue	$ 950	$ 901
Operating Expenses		
Sales and marketing	92,700	103,318
Research and development	40,448	31,468
General and administrative expenses	4,400,253	470,563
Amortization	16,000	16,000
Total operating expenses	(4,549,401)	(621,349)
Other (expense) income	(112,534)	—
Net (loss)	(4,660,985)	$ (620,448)

Net Loss Attributable to Legacy Cardio

Cardio's net loss attributable for the year ended December 31, 2022, was $4,660,985 as compared to $620,448 for the year ended December 31, 2021, an increase of $4,040,537 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, 2022 was $950 compared to $901 for the year ended December 31, 2021. Revenue was generated through the Elicity telemedicine platform.

Sales and Marketing

Expenses related to sales and marketing for the year ended December 31, 2022 were $92,700 as compared to $103,318 for the year ended December 31, 2021, a decrease of $10,618. The overall decrease was due to a decrease in outsourced sales and marketing contracting related to the launching of our first product, Epi+Gen CHD™ in January 2021 as opposed to an increase in 2022 of hiring of staff utilized for sale and marketing efforts.

Research and Development

Research and development expense for year ended December 31, 2022, was $40,448 as compared to $31,468 for year ended December 31, 2021, an increase of $8,980. The increase was attributable to laboratory runs performed in the 2022 period, whereas less laboratory runs were performed in the corresponding period in 2021.

General and Administrative Expenses

General and administrative expenses for the year ended December 31,2022 were $4,400,253 as compared to $470,563 for the year ended December 31, 2021, an increase of $3,929,690. The overall increase is primarily due to an increase in personnel and legal and accounting expenses related to financing and merger transactional activity.

Amortization

Amortization expense for year ended December 31, 2022 was $16,000 as compared to $16,000 for the year ended December 31, 2021. The total amortization expense includes the amortization of intangible assets.

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.

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, we issued and sold to YA II PN, Ltd. ("Yorkville") a Convertible Debenture in the principal amount of $5.0million for a purchase price of $4.5 million (the "First YA Convertible Debenture") to provide additional liquidity. Pursuant to the YA Securities Purchase Agreement, the parties further agreed that we will issue and sell to Yorkville, and Yorkville will purchase from us, a second YA Convertible Debenture in the principal amount of $6.2 million for a purchase price of $5.58 million, subject to the satisfaction or waiver of the conditions set forth in the YA Securities Purchase Agreement. The conditions include, but are not limited to: (i) the SEC shall have declared effective a resale registration statement covering shares of Common Stock issuable upon conversion of the First YA Convertible Debenture; and (ii) we shall have obtained stockholder approval for the issuance of the shares of Common Stock issuable upon conversion of the YA Convertible Debentures that would be in excess of the "Exchange Cap" (as defined in the YA Securities Purchase Agreement).

Our primary cash needs are for day-to-day operations, to fund working capital requirements, to fund our growth strategy, including investments and acquisitions, and to pay $435,000 of deferred contractual obligations originally incurred by Mana to one of its investment bankers, which is payable on October 25, 2023, as well as other accounts payable.

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 also have negative working capital and stockholders' deficit as of December 31, 2022. Our total current liabilities as of December 31, 2022 are $1,947,770. As noted above, on March 8, 2023, we issued and sold the First YA Convertible Debenture, thereby increasing our current liabilities by $5.0 million, with the expectation that we will issue and sell the Second YA Convertible Debenture in the principal amount of $6.2 million in the second quarter of 2023.

We received less proceeds from the Business Combination than we initially expected. The projections that we prepared in June 2022 in connection with the Business Combination assumed that we would receive at least an aggregate of $15 million in capital from the Business Combination and the Legacy Cardio private placements conducted in 2022 prior to the Business Combination. This base amount anticipated at least $5.0 million in proceeds remaining in the Trust Account following payment of the requested redemptions. At Closing, we received only $4,021 in cash from the Trust Account due to higher than expected redemptions by Mana public stockholders and higher than expected expenses in connection with the Business Combination and residual Mana expenses. Accordingly, we have less cash available to pursue our anticipated growth strategies and new initiatives than we projected. This has caused, and may continue to cause, significant delays in, or limit the scope of, our planned acquisition strategy and our planned product expansion timeline. Our failure to achieve our projected results could harm the trading price of our securities and our financial position, and adversely affect our future profitability and cash flows.

Because of the extremely high rate of redemptions by Mana public stockholders in connection with the Business Combination and higher than anticipated transaction costs, we have almost no Trust fund proceeds available to pursue our anticipated growth strategies and new initiatives, including our acquisition strategy. This has had a material impact on our projected estimates and assumptions and actual results of operations and financial condition. We recorded nominal revenue in 2022 of $950. It is likely that revenue in 2023 will also fall short of the projections. Nevertheless, we believe that the fundamental elements of our business strategy remain unchanged, although the scale and timing of specific initiatives have been temporarily negatively impacted as a result of having significantly less than anticipated capital on hand following the Business Combination.

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 $3.90 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

$4.25 on March 27, 2023. 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, 2022 totaled $4,117,521 as compared to $512,767 at December 31, 2021, an increase of $3,604,754. The following table shows Cardio's cash flows from operating activities, investing activities and financing activities for the stated periods:

	2022	2021
Net cash used in operating activities	$ 5,090,968	$ 585,291
Net cash used in investing activities	368,001	364,029
Net cash provided by financing activities	9,063,723	1,225,000

Cash Used in Operating Activities

Cash used in operating activities for the year ended December 31, 2022 was $5,090,968, as compared to $585,291 for the year ended December 31, 2021. 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, 2022, was $368,001 compared to $364,029 for the year ended December 31, 2021. 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, 2022 was $9,063,723 as compared to $1,225,000 for the year ended December 31, 2021. This change was due to $11,986,037 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 placement agent fees, during the year ended December 31, 2022.

Off-Balance Sheet Financing Arrangements

We did not have any off-balance sheet arrangements as of December 31, 2022.

Contractual Obligations

The following summarizes Cardio's contractual obligations as of December 31, 2022 and the effects that such obligations are expected to have on its liquidity and cash flows in future periods:

Deposit for Acquisition

On April 14, 2021, Legacy Cardio deposited $250,000 with an escrow agent in connection with a planned business acquisition. Legacy Cardio subsequently decided to terminate the acquisition and recorded expenses of $112,534 in connection with the termination, which amount is presented as other expenses in the consolidated statements of operations. The remaining escrow balance of $137,466 was returned to Legacy Cardio on July 26, 2022.

Related Party Transactions

The Company reimburses Behavioral Diagnostic, LLC ("BDLLC"), a company owned by its Chief Medical Officer for a portion of the salaries of the Company's Chief Executive Officer and its Chief Technology Officer, who is the husband of the CEO. Payments to BDLLC for salaries totaled $83,767 and $0 for the years ended December 31, 2021 and 2022, respectively.

Prior Mana Obligations to its Investment Bankers

See "*Recent Developments – Business Combination*" above for a discussion of the contractual obligations due and payable on October 25, 2023 to Ladenburg/I-Bankers and Benchmark in the aggregate amount of $928,500 for deferred investment banking fees originally entered into by Mana prior to the Business Combination, as reduced at and after the closing of the Business Combination. On March 25, 2023, Ladenburg offered the Company a 15% early pay discount on the balance due. On March 27, 2023, we accepted the early pay discount and paid Ladenburg the net balance due and payable of $419,475. The balance of $435,000 owed to Benchmark remains due and payable on October 25, 2023.

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. In this regard, the Company and Benchmark are in discussions regarding whether Benchmark might have any rights arising from the Company having entered into the convertible debenture financing in March 2023. No legal proceedings have been instigated, and the parties are continuing to discuss a resolution to this matter.

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 2023, 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. 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.

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 2 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, Cardio Diagnostics, LLC. 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 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 hosts its product, Epi+Gen CHD™ on InTeleLab's Elicity platform (the "Lab"). The Lab collects payments from patients upon completion of eligibility screening. Patients then send their samples to MOgene, a high complexity CLIA lab, which perform the biomarker assessments. Upon receipt of the raw biomarker data from MOgene, the Company performs all quality control, analytical assessments and report generation and shares test reports with the Elicity healthcare provider via the Elicity platform. Revenue is recognized upon receipt of payments from the Lab for each test at the end of each month.

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 are in the process of evaluating its patents' estimated useful life and will begin amortizing the patents when they are brought to the market or otherwise commercialized.

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, 2022, we were not subject to any market or interest rate risk.

Item 8. Financial Statements and Supplemental Data

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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, 2022 and 2021, and the related consolidated statements of operations, changes in stockholders' equity, and cash flows for the years then ended, 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, 2022 and 2021, and the results of its operations and its cash flows for the years then ended, in conformity with accounting principles generally accepted in the United States of America.

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
March 31, 2023

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

	December 31, 2022	
Assets		
Current assets:		
Cash	$ 4,117,521	$ 512,767

Deposit for acquisition	—	250,000
Accounts receivable	—	901
Prepaid expenses and other current assets	1,768,366	39,839
Total current assets	5,885,887	803,507
Long-term assets		
Intangible assets, net	37,333	53,333
Deposits	4,950	—
Patent costs	321,308	245,154
Total assets	$ 6,249,478	$ 1,101,994
Liabilities and Shareholders' Equity		
Current liabilities:		
Accounts payable and accrued expenses	$ 1,098,738	$ 33,885
Finance agreement payable	$ 849,032	—
Total liabilities	1,947,770	33,885
Stockholder's equity		
Preferred stock, $0.00001 par value; authorized - 100,000,000 shares; 0 shares issued and outstanding as of December 31, 2022 and 2021, respectively	—	—
Common stock, $0.00001 par value; authorized - 300,000,000 shares; 9,514,743 and 1,232,324 shares issued and outstanding as of December 31, 2022 and 2021, respectively	95	
Additional paid-in capital	10,293,159	2,398,547
Accumulated deficit	(5,991,546)	(1,330,561)
Total stockholders' equity	4,301,708	1,068,109
Total liabilities and stockholders' equity	$ 6,249,478	$ 1,101,994

See accompanying notes to the consolidated financial statements.

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

	2022	2021
Revenue	$ 950	$ 901
Operating expenses		
Sales and marketing	92,700	103,318
Research and development	40,448	31,468
General and administrative expenses	4,400,253	470,563
Amortization	16,000	16,000
Total operating expenses	4,549,401	621,349
Loss from operations	(4,548,451)	(620,448)
Other expenses		
Acquisition related expense	(112,534)	—
Loss fom operations before provision for income taxes	(4,660,985)	(620,448)
Provision for income taxes	—	—
Net loss	$ (4,660,985)	$ (620,448)
Basic and fully diluted income (loss) per common share:		
Net loss per common share	$ (1.51)	$ (.53)
Weighted average common shares outstanding - basic and fully diluted	3,087,683	1,163,222

See accompanying notes to the consolidated financial statements.

CONSOLIDATED STATEMENTS OF CHANGES IN STOCKHOLDERS' EQUITY
YEARS ENDED DECEMBER 31, 2022 AND 2021

	Common stock		Additional Paid-in	Accumulated	
	Shares	Amount	Capital	Deficit	Totals
Balances, December 31, 2020	3,599,712	$ 36	$ 770,442	$ (710,113)	$ 60,365
Common stock issued for cash	314,489	3	1,224,997	—	1,225,000
Placement agent fee	—	—	(105,000)	—	(105,000)
Stock-based compensation	172,905	2	59,998	—	60,000
SAFE agreements converted to common stock	136,388	1	451,470	—	451,471
Adjustment to patent deposits contributed by shareholders	—	—	(3,279)	—	(3,279)
Net loss				(620,448)	(620,448)
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

See accompanying notes to the consolidated financial statements.

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

	2022	2021
CASH FLOWS FROM OPERATING ACTIVITIES:		
Net loss	$ (4,660,985)	$ (620,448)
Adjustments to reconcile net loss to net		
cash used in operating activities		
Amortization	16,000	16,000
Acquisition related expense	112,534	—
Stock-based compensation expense	—	60,000
Adjustment to patent deposits contributed by shareholders	—	(3,279)
Changes in operating assets and liabilities:		
Accounts receivable	901	(901)
Prepaid expenses and other current assets	(690,821)	(31,009)
Deposits	(4,950)	—
Accounts payable and accrued expenses	136,353	(5,654)
NET CASH USED IN OPERATING ACTIVITIES	(5,090,968)	(585,291)
CASH FLOWS FROM INVESTING ACTIVITIES:		
Deposit for acquisition	—	(250,000)
Cash acquired from acquisition	4,021	—
Repayment of deposit for acquisition	137,466	—
Payments for notes receivable	(433,334)	—
Patent costs incurred	(76,154)	(114,029)
NET CASH USED IN INVESTING ACTIVITIES	(368,001)	(364,029)
CASH FLOWS FROM FINANCING ACTIVITIES:		
Proceeds from sale of common stock	11,986,037	1,120,000
Proceeds from stock to be issued	—	105,000

Payments of finance agreement	(188,674)	—
Payments of recapitalization transaction costs	(1,535,035)	—
Payments of placement agent fee	(1,198,604)	—
NET CASH PROVIDED BY FINANCING ACTIVITIES	9,063,723	1,225,000
NET INCREASE IN CASH	3,604,755	275,680
CASH - BEGINNING OF YEAR	512,767	237,087
CASH - END OF YEAR	$ 4,117,521	$ 512,767
SUPPLEMENTAL DISCLOSURES OF CASH FLOW INFORMATION:		
Cash paid during the year for:		
Interest	$ 5,829	$ —
Non-cash investing and financing activities:		
Common stock issued for acquisition	$ 754	$ —
Liabilities assumed in acquisition	$ 928,500	—
Financing agreement entered into for prepaid insurance	1,037,706	
Common stock issued for SAFE agreements	—	451,471

CARDIO DIAGNOSTICS HOLDINGS, INC.
Notes to Consolidated Financial Statements
Years Ended December 31, 2022 and 2021

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. 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 October 25, 2022, pursuant to a Merger Agreement, Mana Capital Acquisition Corp. ("Mana"), a special purpose acquisition company incorporated under the laws of the state of Delaware merged with and into the Company, with the Company surviving the merger as a wholly-owned subsidiary of Mana Capital. Subsequent to the merger, Mana changed its name to Cardio Diagnostics Holdings Inc.

Note 2 – Merger Agreement and Reverse Recapitalization

As discussed in Note 1, on October 25, 2022, the Company and Mana 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.

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 common shares were reversed and the Mana common shares totaling 9,514,743 were recorded, as described in Note 7. 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 Cardio Diagnostics, LLC. 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 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 will host its product, Epi+Gen CHD™ on InTeleLab's Elicity platform ("the Lab"). The Lab collects payments from patients upon completion of eligibility screening. Patients then send their samples to MOgene, a high complexity CLIA lab, which perform the biomarker assessments. Upon receipt of the raw biomarker data from MOgene, the Company performs all quality control, analytical assessments and report generation and shares test reports with the Elicity healthcare provider via the Elicity platform. Revenue is recognized upon receipt of payments from the Lab for each test at the end of each month.

The Company will account 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.

Research and Development

Research and development costs are expensed as incurred. Research and development costs charged to operations for the years ended December 31, 2022 and 2021 were $40,448 and $31,468, respectively.

Advertising Costs

The Company expenses advertising costs as incurred. Advertising costs of $92,700 and $103,318 were charged to operations for the years ended December 31, 2022 and 2021, 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 not have any cash equivalents as of December 31, 2022 and 2021. 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.

Patent Costs

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 are in the process of evaluating its patents' estimated useful life and will begin amortizing the patents when they are brought to the market or otherwise commercialized.

Long-Lived Assets

The Company assesses the valuation of components of its property and equipment and other 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.

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 condensed consolidated financial statements as a result of future adoption.

Note 4 – Intangible Assets

The following tables provide detail associated with the Company's acquired identifiable intangible assets:

	As of December 31, 2022			
	Gross Carrying Amount	Accumulated Amortization	Net Carrying Amount	Weighted Average Useful Life (in years)
Amortized intangible assets:				
Know-how license	$ 80.000	$ (42,667)	$ 37,333	5
Total	$ 80.000	$ (42,667)	$ 37,333	

Amortization expense charged to operations was $16,000 for the years ended December 31, 2022 and 2021, respectively.

Note 5 – Patent Costs

As of December 31, 2022, the Company has three pending patent applications. The initial patent applications consist of a US patent and international patents filed in six countries. The US patent was granted on August 16, 2022. The EU patent was granted on March 31, 2021. The validation of the EU patent in each of the six countries is pending. Legal fees associated with the patents totaled $321,308 and $245,154 as of December 31, 2022 and 2021, respectively and are presented in the balance sheet as patent costs.

Note 6 – Finance Agreement Payable

On October 31, 2022, 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, 2022. The amount financed of $1,037,706 is payable in 11 monthly installments plus interest at a rate of 6.216% through September 28, 2023. Finance agreement payable was $849,032 at December 31, 2022. $926,658 has been recorded in prepaid expenses and is being amortized over the life of the policy.

Note 7 – 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, 2022 and 2021 as the result would be anti-dilutive.

	Years Ended December 31,	
	2022	2021
Stock warrants	7,954,620	114,924
Stock options	3,256,383	—
Total shares excluded from calculation	11,211,003	114,924

Note 8 – 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 3,256,383 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

The Company sold 744,425 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.

In connection with a private offering memorandum that the Company issued through a placement agent on April 12, 2021, the Company sold 91,761 common shares valued at $13.35 per share to various investors for proceeds totaling $1,225,000 during the year ended December 31, 2021. The Company paid the placement agent $105,000 in cash and issued 23,596 warrants.

On March 10, 2021, the Company issued 50,450 common shares to various consultants for services, valued at $60,000.

On March 15, 2021, the investors converted their SAFE agreements to 39,786 common shares, valued at $451,471.

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 and May 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.

From May 23, 2022 through September 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.

Warrant activity during the years ended December 31, 2022 and 2021 follows:

	Warrants Outstanding	Weighted Average Exercise Price	Average Remaining Contractual Life (Years)
Warrants outstanding at December 31, 2020	52,000	$ 13.35	13.76
Warrants granted	62,924	13.35	
Warrants outstanding at December 31, 2021	114,924	13.35	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)	13.35	
Warrants outstanding at December 31, 2022	7,954,620	$ 9.63	4.46

Options

In May 2022, the Legacy Cardio granted 513,413 stock options to officers, directors and employees 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 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 the merger with Mana.

Note 9 - 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, 2022 is as follows:

Statutory U.S. federal income tax rate	(21.0)%
Change in Valuation Allowance	21.0%
Effective tax rate	0.0%

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

	2022	2021

Deferred Tax Assets:		
Net Operating Losses	$ 1,611,487	$ 146,578
Other	1,962	—
Stock-based compensation	186,611	197,895
Total deferred tax assets	1,800,060	344,473
Deferred Tax Liabilities	—	—
Valuation Allowance	(1,800,060)	(344,473)
Net deferred tax assets	$ —	$ —

As of December 31, 2022, the Company had federal net operating loss carryforwards of approximately $5.3 million which may be carried forward indefinitely, and state net operating loss carryforwards of approximately $5.3 million which expire at various dates from 2040 through 2042. 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, 2022 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, 2022.

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, 2022 and 2021, 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 NOL's 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 10 – Commitments and Contingencies

Deposit For Acquisition

On April 14, 2021, the Company deposited $250,000 with an escrow agent in connection with a planned business acquisition. The Company subsequently decided to terminate the acquisition and recorded expenses of $112,534 in connection with the termination and is presented as other expenses in the consolidated statements of operations. The remaining escrow balance of $137,466 was returned to the Company on July 26, 2022.

Prior Relationship 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. In this regard, the Company and Benchmark are in discussions regarding the convertible debenture financing the Company entered into in March 2023 whether Benchmark might have any rights arising from the Company having entered into the convertible debenture financing in March 2023. No legal proceedings have been instigated, and the parties are continuing to discuss a resolution to this matter.

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 2023, 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. 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.

Note 11 - Related Party Transactions

The Company reimburses Behavioral Diagnostic, LLC ("BDLLC"), a company owned by its Chief Medical Officer for salaries of the Company's CEO and its senior data scientist, who is the husband of the CEO. Payments to BDLLC for salaries totaled $0 and $79,920 for the years ended December 31, 2022 and 2021, respectively.

Note 12 – Subsequent Events

The Company evaluated its December 31, 2022 consolidated financial statements for subsequent events through the date the consolidated financial statements were issued.

Securities Issued

On March 2, 2023, a stockholder exercised warrants for 100,000 common shares for total proceeds of $390,000.

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 common shares of the Company and are subject to various contingencies being satisfied as set forth in the Securities Purchase Agreement. The Company received 90% of the proceeds, with a $5 million convertible debenture being entered into at the initial closing of which the Company received $4.5 million.

Prepayment of Deferred Contractual Obligation

On March 27, 2023, the Company accepted an early pay discount offered by one of its investment bankers with respect to a deferred payment obligation incurred by Mana in connection with its initial public offering and paid that investment banker the net balance due and payable of $419,475.

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, 2022, 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.

For purposes of filing our first annual report with the SEC following our reverse acquisition with a public company, per the guidance provided in Section 215.02 of the SEC's Compliance

and Disclosure Interpretations, we have not included management's report on internal controls over financial reporting pursuant to Section 404 of the Sarbanes-Oxley Act. We will be required to disclose changes made in our internal controls and procedures in our quarterly reports beginning with the report for the period ending March 31, 2023 and provide management's report on internal controls over financial reporting beginning with the report for the year ending December 31, 2023. Our independent registered public accounting firm will not be required to formally attest to the effectiveness of our internal control over financial reporting pursuant to Section 404 until the later of (a) the year following our first annual report required to be filed with the SEC or (b) the year following a year during which we cease to be considered an "emerging growth company," as defined in Section 2(a) of the Securities Act of 1933, as modified by the Jumpstart Our Business Startups Act of 2012.

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, 2022 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

Item 9B. Other Information.

None

Item 9C. Disclosure Regarding Foreign 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 March 27, 2023, of our executive officers and members of the Board of Directors.

Name	Age	Position
Executive Officers		
Meeshanthini (Meesha) V. Dogan, PhD	33	Chief Executive Officer and Director
Robert (Rob) Philibert, MD PhD	61	Chief Medical Officer and Director
Elisa Luqman, JD MBA	58	Chief Financial Officer
Timur Dogan, PhD	35	Chief Technology Officer
Khullani Abdullah, JD	39	Vice President of Revenue and Strategy
Non-Employee Directors		
Warren Hosseinion, MD	51	Non-Executive Chairman
James Intrater	59	Director
Stanley K. Lau, MD	67	Director
Oded Levy	64	Director
Brandon Sim	29	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 10 years' experience in bridging medicine, engineering and artificial intelligence towards building solutions to fulfill unmet clinical needs such as in cardiovascular disease prevention. 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 (European Patent Granted in March 2021). In 2017, Dr. Dogan founded Legacy Cardio to commercialize this technology through a series of 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, has worked its way to become a technology leader in cardiovascular diagnostics, introduced its first product for marketing testing in January 2021, 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.

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 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 since May 2022 and was on Legacy Cardio's Board of Directors since November 2020. In March 2021, 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 is also currently the President and a director of Nutex, positions he has held since April 2022. Dr. Hosseinion is a Co-Founder of Apollo Medical Holdings, Inc. (Nasdaq: AMEH) and served as a member of the Board of Directors of Apollo Medical Holdings, Inc. since July 2008, the Chief Executive Officer of Apollo Medical Holdings, Inc. from July 2008 to December 2017, and the Co-Chief Executive Officer of Apollo Medical Holdings, Inc. from December 2017 to March 2019. In 2001, Dr. Hosseinion co-founded ApolloMed. 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.

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.

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.

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.

Brandon Sim has served as a member of the Company's Board of Directors since consummation of the Business Combination in October 2022. He is the Co-Chief Executive Officer of Apollo Medical Holdings, Inc. where he is focused on transforming healthcare delivery for physicians and patients. He is responsible for ApolloMed's overall strategy, growth, operations, and technology innovation. Since joining ApolloMed in 2019, he has also served as Chief Operating Officer, Chief Technology Officer and Vice President of Engineering. Prior to joining ApolloMed, Mr. Sim served as Quantitative Researcher at Citadel Securities from 2015 to 2019. From 2012 to 2015, Mr. Sim co-founded and served as Chief Technology Officer at Theratech, a medical device company focused on developing a low-cost, simple-to-use patch for automated drug delivery. Mr. Sim was a member of the board of directors of Clinigence Holdings, Inc. between October 2021 and April 2022. Mr. Sim received his Master of Science in Computer Science and Engineering and Bachelor of Arts in Statistics and Physics, Magna Cum Laude with High Honors, from Harvard University.

Family Relationships

Other than Meeshanthini Dogan and Timur Dogan, who are wife and husband, there 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 Stanley K. Lau, MD, Oded Levy, James Intrater and Brandon Sim, 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 James Intrater, Oded Levy, and Brandon Sim, 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 Levey 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 Brandon Sim, with Mr. Sim 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 that 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, 2022, 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 "2022 Summary Compensation Table" below. For the year ended December 31, 2022, our "named executive officers" ("NEOs") and their positions were as follows:

- Meeshanthini V. Dogan, Chief Executive Officer;
- Warren Hosseinion, Chairman of the Board; and
- Elisa Luqman, Chief Financial Officer.

As required by SEC rules, Cardio's "NEOs" for 2022 also include Jonathan Intrater, who was the chief executive officer of Mana prior to the closing of the Business Combination. Mr. Intrater did not receive any employee compensation during the year ended December 31, 2022. Accordingly, the following executive compensation disclosure omits Mr. Intrater and includes only the compensation of Cardio's NEOs as of the closing of the Business Combination.

2022 Summary Compensation Table

The following table sets forth information concerning the compensation of our named executive officers for fiscal years ended December 31, 2021 and December 31, 2022.

Current Officers Name & Principal Position	Year	Salary ($)	Bonus [4]	Stock [2]	Option Awards [3]	All Other Compensation ($)	Total
		($)	($)	($)	($)	($)	($)
Meeshanthini V. Dogan, CEO	2022	175,000	250,000	0	4,105,856	8,897(1)	4,539,753
	2021	75,000	0	0	0	5,694(1)	80,694
Warren Hosseinion, Chairman	2022	50,000	250,000	0	2,052,928	30,000(5)	2,382,928
	2021	0	0	0	0	0	0
Elisa Luqman, CFO	2022	55,833	100,000	0	1,026,464	20,000(5)	1,202,297
	2021	0	0	40,000	0	0	40,000

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

(2) Discretionary stock grants made by Legacy Cardio in 2021 for performance. These amounts reflect the grant date fair values of performance awards. The amounts reported do not reflect compensation actually received.

(3) Discretionary stock option grants 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 options became immediately vested at that time. These 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.

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

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

Narrative to the Summary Compensation Table

2022 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 2022, 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."

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.

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 2022.

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 into stock options in the Company under the Cardio Diagnostics Holdings, Inc. 2022 Equity Incentive Plan (the "2022 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. 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 Plan, as adopted, provides for the grant of up to 3,256,383 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 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 Plan on January 1, 2023. 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.

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, 2022. 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	685,452	—	—	$ 3.90	5/6/2032
Warren Hosseinion	342,726	—	—	$ 3.90	5/6/2032
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

During 2021 and 2022, Cardio did not compensate its directors for service as a director. Cardio reimburses its non-employee directors for reasonable travel and out-of-pocket expenses incurred in connection with attending board of director and committee meetings or undertaking other business on behalf of Cardio.

The newly-constituted compensation committee following the consummation of the Business Combination has not yet determined the type and level of compensation, if any, for those persons serving as members of the Board of Directors.

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 March 27, 2023 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 9,614,743 shares of the Company's Common Stock outstanding as of March 27, 2023.

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		
YA II PN, Ltd.(2)	9,090,910	48.6%
Meeshanthini V. Dogan(3)	2,422,599	23.4%
Robert Philibert(4)	2,129,881	21.0%
BD Holding, Inc.(5)	1,586,464	16.5%
Warren Hosseinion(6)	458,779	4.6%
Elisa Luqman(7)	229,303	2.3%
James Intrater	—	—
Stanley K. Lau	—	—
Oded Levy	—	—
Brandon Sim	—	—
All Executive Officers and Directors as a Group (10 individuals)(8)	5,255,116	46.2%

* Less than 1%.

(1) Unless otherwise noted, the address for the persons in the table is 400 N. Aberdeen St., Suite 900, Chicago IL 60642.

(2) Includes 9,090,910 shares potentially issuable upon conversion of the First YA Convertible Debenture but does not include additional shares that will be issuable upon conversion of the Second YA Convertible Debenture, which has not yet been issued as of the date of the table. The Second Convertible Debenture in the amount of $6.2 million is issuable upon the satisfaction of certain conditions, including, without limitation, the effectiveness of a registration statement covering the resale of the shares issuable upon conversion of the YA Convertible Debentures. The number of shares of Common Stock that may actually be acquired by YA II PN, Ltd. (the "Yorkville Investor") pursuant to the YA Convertible Debentures is not currently known. Any conversion of the YA Convertible Debentures into shares of Common Stock is limited by the terms of the YA Convertible Debentures to such number of shares of Common Stock that would not result in the Yorkville Investor, together with shares held by the Yorkville Investor and its affiliates, beneficially owning (as determined in accordance with Rule 13d-3 of the Securities Exchange Act of 1934, as amended) in excess of 4.99% of the number of shares of Common Stock. Upon issuance of $11.2 million in principal amount of YA Convertible Debentures, and assuming receipt of required stockholder approval, the Yorkville Investor could potentially be issued up to 20,363,637 shares of Common Stock, which is calculated based on 100% of the principal conversions being effected at $0.55 per share, subject to adjustment (the "Floor Price"). The share total in the above table assumes conversion of the First YA Convertible Debenture at the Floor Price. Actual conversion prices will depend on the trading price of our Common Stock on or about the date of conversion, which conversions may be effected from time to time, once this Annual Report on Form 10-K is filed. Until receipt of stockholder approval required by Nasdaq Marketplace Rules 5635(b) and (d), the Yorkville Investor may not be issued more than 1,921,987 shares. The Yorkville Investor is a fund managed by Yorkville Advisors Global, LP ("Yorkville LP"). Yorkville Advisors Global II, LLC ("Yorkville LLC") is the General Partner of Yorkville LP. All investment decisions for the Yorkville Investor are made by Yorkville LLC's President and Managing Member, Mark Angelo. The business address of the Yorkville Investor is 1012 Springfield Avenue, Mountainside, NJ 07092.

(3) Includes 110,094 shares of common stock and 40,589 shares issuable upon exercise of currently-exercisable options owned directly by Dr. Dogan's spouse, Timur Dogan, who is an executive officer. Also includes 685,452 shares of Common Stock issuable upon exercise of Dr. Dogan's options that are currently exercisable. 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.

(4) Shares of common stock reflected in the table as beneficially owned by Dr. Philibert include: (i) 7,601 shares of Common Stock owned by Dr. Philibert's wife, as to which he may be deemed to be the beneficial owner but as to which he disclaims beneficial ownership except to the extent of his pecuniary interest therein; (ii)(a) 1,586,464 shares of Common Stock owned by BD Holding, Inc. (see Note (5) below), and (b) 14,126 shares of Common Stock owned by Behavioral Diagnostics, Inc., a corporation controlled by Dr. Philibert and in which he serves as chief executive officer. Dr. Philibert disclaims beneficial ownership of all such indirectly-owned shares except to the extent of his pecuniary interest in such corporations. Also includes 514,089 shares of Common Stock issuable upon exercise of options that are currently exercisable.

(5) BD Holding, Inc. is an S Corporation owned by Robert Philibert and his wife, Ingrid Philibert. Robert Philibert is the sole officer and director and has voting and dispositive control over the securities of BD Holding, Inc. The address for BD Holding, Inc. is 15 Prospect Place, Iowa City, IA 52246.

(6) Includes 342,726 shares of the Common Stock issuable upon exercise of options that are currently exercisable.

(7) Includes 171,363 shares of common stock issuable upon exercise of options that are currently exercisable.

(8) Includes 1,754,219 shares of common stock issuable upon exercise of options that are currently exercisable.

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

The following includes a summary of transactions since January 1, 2021 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." We also describe below certain other transactions with our directors, executive officers and stockholders.

As part of an earlier friends and family round of financing by Cardio, Robert Philibert, Co-Founder, Chief Medical Officer and Director of the Company, personally invested $25,000 as part of the Cardio's early friends and family round. In addition, Dr. Philibert's spouse and other family members invested $150,000. Finally, Behavioral Diagnostics, LLC, an affiliate of Dr. Philibert, invested $46,471 via the SAFE instrument in this earlier round. These SAFEs were converted to common stock effective as of April 6, 2022.

Certain research and development laboratory runs were performed on a fee-for-service basis at Dr. Philibert's academic laboratory at the University of Iowa. Cardio paid $31,468 and $1,500 to the lab in 2021 and 2020.

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, 2022 and 2021

	For the Year Ended December 31, 2022	For the Year Ended December 31, 2021
Audit Fees (1)	$ 62,000	$ 22,500
Audit-Related Fees (2)	—	—
Tax Fees (3)	—	—
All Other Fees (4)	—	—
Total Fees	$ 62,000	$ 22,500

(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, 2021 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 2022, 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, 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:

		Incorporation by Reference		
Exhibit Number	Description	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)	S-4/A	2.1	10/4/22
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	S-4/A	2.2	10/4/22
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	Second Amended and Restated Certificate of Incorporation of Cardio Diagnostics Holdings, Inc., dated October 25, 2022	8-K	3.1	10/31/22
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	Convertible Debenture, dated March 8, 2023	8-K	4.1	3/13/23
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 Lock-up Agreement	S-4	10.6	5/31/22
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	8-K	10.4	10/31/22
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	10.19	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	Letter Agreement, dated November 22, 2021, by and among the Company, its former independent directors and the Sponsor	8-K	10.1	11/26/21
10.15	Letter Agreement, dated November 22, 2021 by and between the Company and its former chief executive officer	8-K	10.2	11/26/21
10.16	Securities Purchase Agreement, dated March 8, 2023, by and between the registrant and YA II PN, Ltd.	8-K	10.1	03/13/23
10.17	Registration Rights Agreement, dated March 8, 2023, by and between the registrant and YA II PN, Ltd.	8-K	10.3	03/13/23
10.18*	Engagement Letter, dated as of May 13, 2022, between Mana Capital Acquisition Corp. and The Benchmark Company, LLC			
10.19*	Amendment No. 1 to Engagement Letter, dated November 14, 2022, between the Registrant and The Benchmark Company, LLC			
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			
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.

+ 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.

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: March 31, 2023

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	Chief Executive Officer and Director	March 31, 2023
/s/ Elisa Luqman Elisa Luqman	Chief Financial Officer and Principal Accounting Officer	March 31, 2023
/s/ Warren Hosseinion, MD Warren Hosseinion, MD	Director (Chairman of the Board)	March 31, 2023
/s/ James Intrater James Intrater	Director	March 31, 2023
/s/ Stanley K. Lau Stanley K. Lau	Director	March 31, 2023
/s/ Oded Levy Oded Levy	Director	March 31, 2023
/s/ Robert Philibert Robert Philibert	Director	March 31, 2023
/s/ Brandon Sim Brandon Sim	Director	March 31, 2023

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 second 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 securities as of December 31, 2022.

General

As of the date of our Annual Report on Form 10-K for the fiscal year ended December 31, 2022, 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. As of December 31, 2022, 9,514,743 shares of common stock are outstanding. No shares of preferred stock are currently outstanding. The following description summarizes all of the material terms of our securities. Because it is only a summary, it may not contain all the information that is important to you. For a complete description you should refer to our certificate of incorporation, bylaws, and the warrant agreement, all of which are filed as exhibits to the Annual Report on Form 10-K of which this Exhibit 4.5 is a part.

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.

Preferred Stock (not a class of securities registered under Section 12 of the Exchange Act)

There are no shares of preferred stock outstanding. Our certificate of incorporation filed with the State of Delaware authorizes the issuance of 100,000,000 shares of preferred stock, $0.00001 par value per share, with such designation, rights and preferences as may be determined from time to time by our board of directors. Accordingly, our board of directors is empowered, without stockholder approval, to issue preferred stock with dividend, liquidation, conversion, voting or other rights which could adversely affect the voting power or other rights of the holders of common stock. In addition, the preferred stock could be utilized as a method of discouraging, delaying or preventing a change in control of us. Although we do not currently intend to issue any shares of preferred stock, we reserve the right to do so 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.

Private Warrants (not a class of securities registered under Section 12 of the Exchange Act)

In addition to our public warrants, at December 31, 2022, we have the following privately-issued warrants, none of which are registered under Section 12 of the Exchange Act:

- 2,500,000 warrants sold to our former sponsor, which are exercisable through October 25, 2027 at $11.50 per share, subject to adjustment for stock splits, reverse stock splits and other similar events of recapitalization;
- 931,265 warrants, exercisable at $3.90 per share, subject to adjustment for stock splits, reverse stock splits and other similar events of recapitalization, which were sold in a private placement by Legacy Cardio in 2021 and 2022, having an expiration date five years from the date of issuance; and
- 1,273,362 warrants, exercisable at $6.21 per share, subject to adjustment for stock splits, reverse stock splits and other similar events of recapitalization, which were sold in a private placement by Legacy Cardio in 2022, having an expiration date five years from the date of issuance.

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 10.18

[Logo]
BENCHMARK

May 13, 2022

STRICTLY CONFIDENTIAL

Mana Capital Acquisition Corp.
Jonathan Intrater
Chief Executive Officer
8 The Green
Suite 12490
Dover, DE 19901
Dear Mr. Intrater:

This letter (the "Agreement") constitutes the agreement between Mana Capital Acquisition Corp. (the "Company") and The Benchmark Company, LLC ("Benchmark") that Benchmark shall serve as the exclusive financial advisor in connection with a transaction or related series or combination of transactions involving an acquisition by the Company of the stock or all or substantially all of the assets of, or a significant division of, a third party, including by way of (a) a merger or acquisition of stock, (b) a recapitalization or consolidation, (c) a joint venture (providing substantially the benefits of an acquisition, or providing for the potential purchase of the joint venture assets of the third party), (d) an acquisition of assets, (e) a licensing or similar agreement or arrangement (providing substantially the benefits of an acquisition, or providing for the potential purchase of the licensed or similarly treated assets of the third party) or (f) another strategic transaction of similar nature (any or all of the foregoing, an "M&A Transaction").

If an offering is undertaken by the Company, or the Company engages in a recapitalization or refinancing transaction, Benchmark shall serve as lead manager or exclusive placement agent (collectively, with the services in respect of a potential M&A Transaction, the "Services") for the Company in connection with such offer and placement (the "Offering") by the Company of securities of the Company (the "Securities"). The terms of any Offering and the Securities shall be mutually agreed upon by the Company and the investors therein and nothing herein implies that Benchmark would have the power or authority to bind the Company or an obligation for the Company to issue any Securities or complete such Offering. The Company expressly acknowledges and agrees that the execution of this Agreement does not constitute a commitment by Benchmark to purchase Securities and does not ensure the successful placement of Securities or any portion thereof or the success of Benchmark with respect to securing any other financing on behalf of the Company.

A. Fees and Expenses. In connection with the Services described above, the Company shall pay to Benchmark the following compensation:

1. M&A Transaction Related Fee. If an M&A Transaction is effected during the Term (as hereafter defined) or the Tail Period (as hereafter defined), with a company, firm, o with whom Benchmark had substantive discussions, correspondence or meetings on behalf of the Company (including any affiliates of any such parties), the Company shall pay Benchmark a cash fee for its services hereunder (the "Advisory Fee")") equal to 1.5% of the Aggregate Consideration (as defined below) paid in connection with such M&A Transaction. "The Advisory Fee shall be payable at the closing of the M&A Transaction, provided that any Advisory Fee in respect of contingent amounts shall be payable when such contingent amounts are payable pursuant to the applicable transaction documents. The 12-month period following the expiration or termination of the Term of this Agreement shall be the “Tail Period”.

4.[sic] Expenses. In addition to any fees payable to Benchmark hereunder, the Company agrees to reimburse Benchmark for all reasonable travel and other out-of-pocket expens connection with Benchmark's engagement, including the reasonable fees and expenses of Benchmark's counsel.

B. Term and Termination of Engagement. The term (the "Term") of Benchmark's engagement will begin on the date hereof and end on the earlier of six months from the date hereof o days after the receipt by either party hereto of written notice of termination. Notwithstanding anything to the contrary contained herein, the provisions concerning indemnification, contribution and the Company's obligations to pay fees and reimburse expenses contained herein will survive any expiration or termination of this Agreement.

C. Use of Information. The Company will furnish Benchmark such written information as Benchmark reasonably request in connection with the performance of its services hereunde Company understands, acknowledges and agrees that, in performing its services hereunder, Benchmark will use and rely entirely upon such information as well as publicly available information regarding the Company and other potential parties to a Transaction and that Benchmark do not assume responsibility for independent verification of the accuracy or completeness of any information, whether publicly available or otherwise furnished to it, concerning the Company or otherwise relevant to a Transaction, including, without limitation, any financial information, forecasts or projections considered by Benchmark in connection with the provision of its services.

D. Publicity. In the event of the consummation or public announcement of any Transaction, Benchmark shall have the right to disclose its participation in such Transaction, includir without limitation, the placement at its cost of “tombstone" advertisements on its Website and in financial and other newspapers and journals.

E. Securities Matters. The Company shall be responsible for any and all compliance with the securities laws applicable to it, including Regulation D and the Securities Act of 1933, a amended (the "Securities Act"), and Rule 506 promulgated thereunder, and unless otherwise agreed in writing, all state securities ("blue sky") laws. Benchmark agrees to cooperate with counsel to the Company in that regard.

F. Indemnity.

1. In connection with the Company's engagement of Benchmark for Services, the Company hereby agrees to indemnify and hold harmless Benchmark and its affiliates, and controlling persons, directors, officers, partners, members, shareholders, agents, registered representatives, registered principals and employees of any of the foregoing (collectively the “Indemnified Persons"), from and against any and all claims, actions, suits, proceedings (including those of shareholders), investigations, damages, liabilities and expenses incurred by any of them (including the reasonable fees and expenses of counsel), as incurred, (collectively a "Claim"), that are (A) related to or arise out of (i) any actions taken or omitted to be taken (including any untrue statements made or any statements omitted to be made) by the Company, or (ii) any actions taken or omitted to be taken by any Indemnified Person in connection with the Company's engagement of Benchmark, or (B) otherwise relate to or arise out of Benchmark's activities on the Company's behalf under Benchmark's engagement, and the Company shall reimburse any Indemnified Person for all expenses (including the reasonable fees and expenses of counsel) as incurred by such Indemnified Person in connection with investigating, preparing or defending any such claim, action suit or proceeding, whether or not in connection with pending or threatened litigation in which any Indemnified Person is a party. The Company will not, however, be responsible for any Claim that is finally judicially determined to have resulted from the gross negligence or willful misconduct of any person seeking indemnification for such Claim. The Company further agrees that no Indemnified Person shall have any liability to the Company for or in connection with the Company's engagement of Benchmark except for any Claim incurred by the Company as a result of such Indemnified Person's gross negligence or willful misconduct.

2. The Company further agrees that it will not, without the prior written consent of Benchmark, settle, compromise or consent to the entry of any judgment in any pending Claim in respect of which indemnification may be sought hereunder (whether or not any Indemnified Person is an actual or potential party to such Claim), unless such settlement, compromise or consent includes an unconditional, irrevocable release of each Indemnified Person from any and all liability arising out of such Claim.

3. Promptly upon receipt by an Indemnified Person of notice of any complaint or the assertion or institution of any Claim with respect to which indemnification is being sou

such Indemnified Person shall notify the Company in writing of such complaint or of such assertion or institution but failure to so notify the Company shall not relieve the Company from any obligation it may have hereunder, except and only to the extent such failure results in the forfeiture by the Company of substantial rights and defenses. If the Company so elects or is requested by such Indemnified Person, the Company will assume the defense of such Claim, including the employment of counsel reasonably satisfactory to such Indemnified Person and the payment of the fees and expenses of such counsel. In the event, however, that legal counsel to such Indemnified Person reasonably determines that having common counsel would present such counsel with a conflict of interest or if the defendant in, or target of, any such Claim, includes an Indemnified Person and the Company, and legal counsel to such Indemnified Person reasonably concludes that there may be legal defenses available to it or other Indemnified Persons different from or in addition to those available to the Company, then such Indemnified Person may employ its own separate counsel to represent or defend him, her or it in any such Claim and the Company shall pay the reasonable fees and expenses of such counsel. Notwithstanding anything herein to the contrary, if the Company fails timely or diligently to defend, contest, or otherwise protect against any Claim, the relevant Indemnified Party shall have the right, but not the obligation, to defend, contest, compromise, settle, assert crossclaims, or counterclaims or otherwise protect against the same, and shall be fully indemnified by the Company therefor, including without limitation, for the reasonable fees and expenses of its counsel and all amounts paid as a result of such Claim or the compromise or settlement thereof. In addition, with respect to any Claim in which the Company assumes the defense, the Indemnified Person shall have the right to participate in the defense of such Claim and to retain his, her or its own counsel therefor at his, her or its own expense.

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4. The Company agrees that if any indemnity sought by an Indemnified Person hereunder is held by a court to be unavailable for any reason then (whether or not Benchma Indemnified Person), the Company and Benchmark shall contribute to the Claim for which such indemnity is held unavailable in such proportion as is appropriate to reflect the relative benefits to the Company, on the one hand, and Benchmark on the other, in connection with Benchmark's engagement referred to above, subject to the limitation that in no event shall the amount of Benchmark's contribution to such Claim exceed the amount of fees actually received by Benchmark from the Company pursuant to Benchmark's engagement. The Company hereby agrees that the relative benefits to the Company, on the one hand, and Benchmark on the other, with respect to Benchmark's engagement shall be deemed to be in the same proportion as (a) the total value paid or proposed to be paid or received by the Company or its stockholders as the case may be, pursuant to a Transaction (whether or not consummated) for which Benchmark is engaged to render services bears to (b) the fee paid or proposed to be paid to Benchmark in connection with such engagement.

5. The Company's indemnity, reimbursement and contribution obligations under this Agreement (a) shall be in addition to, and shall in no way limit or otherwise adversely that any Indemnified Person may have at law or at equity and (b) shall be effective whether or not the Company is at fault in any way.

G. Limitation of Engagement to the Company. The Company acknowledges that Benchmark has been retained only by the Company, that Benchmark is providing Services hereunde independent contractor (and not in any fiduciary or agency capacity) and that the Company's engagement of Benchmark is not deemed to be on behalf of, and is not intended to confer rights upon, any shareholder, owner or partner of the Company or any other person not a party hereto as against Benchmark or any of its affiliates, or any of its affiliates' respective officers, directors, controlling persons (within the meaning of Section 15 of the Securities Act or Section 20 of the Securities Exchange Act of 1934, as amended (the "Exchange Act")), partners, employees, registered principals, registered representatives or agents. Unless otherwise expressly agreed in writing by Benchmark, no one other than the Company is authorized to rely upon this Agreement or any other statements or conduct of Benchmark, and no one other than the Company is intended to be a beneficiary of this Agreement. The Company acknowledges that any recommendation or advice, written or oral, given by Benchmark to the Company in connection with Benchmark's engagement is intended solely for the benefit and use of the Company's management and directors in considering a possible Transaction, and any such recommendation or advice is not on behalf of, and shall not confer any rights or remedies upon, any other person or be used or relied upon for any other purpose. Benchmark shall not have the authority to make any commitment binding on the Company. The Company, in its sole discretion, shall have the right to reject any investor or counterparty introduced to it by Benchmark. The Company agrees that it will perform and comply with the covenants and other obligations set forth in the purchase agreement and related transaction documents, as applicable, between the Company and the investors in the Transaction, and that Benchmark will be entitled to rely on the representations, warranties, agreements and covenants of the Company contained in such purchase agreement and related transaction documents as if such representations, warranties, agreements and covenants were made directly to Benchmark by the Company.

H. Limitation of Benchmark's Liability to the Company. Benchmark and the Company further agree that neither Benchmark nor any of its affiliates or any of their respective officers, directors, controlling persons (within the meaning of Section 15 of the Securities Act or Section 20 of the Exchange Act), partners, employees, registered representatives, registered principals or agents shall have any liability to the Company, its security holders or creditors, or any person asserting claims on behalf of or in the right of the Company (whether direct or indirect, in contract, tort, for an act of negligence or otherwise) for any losses, fees, damages, liabilities, costs, expenses or equitable relief arising out of or relating to this Agreement or the Services rendered hereunder, except for losses, fees, damages, liabilities, costs or expenses that arise out of or are based on any action of or failure to act by Benchmark and that are finally judicially determined to have resulted solely from the gross negligence or willful misconduct of Benchmark.

I. Governing Law. This Agreement shall be governed by and construed in accordance with the laws of the State of New York applicable to agreements made and to be fully perform therein. Any disputes that arise under this Agreement, even after the termination of this Agreement, will be beard only in the state or federal courts located in the City of New York, State of New York. The parties hereto expressly agree to submit themselves to the jurisdiction of the foregoing courts in the City of New York, State of New York. The parties hereto expressly waive any rights they may have to contest the jurisdiction, venue or authority of any court sitting in the City and State ofNew York. In the event of the bringing of any action, or suit by a party hereto against the other party hereto, arising out of or relating to this Agreement, the party in whose favor the final judgment or award shall be entered shall be entitled to have and recover from the other party the costs and expenses incurred in connection therewith, including its reasonable attorneys' fees. Any rights to trial by jury with respect to any such action, proceeding or suit are hereby waived by Benchmark and the Company.

J. Notices. All notices hereunder will be in writing and sent by certified mail, hand delivery, overnight delivery or fax, if sent to Benchmark, to The Benchmark Company, LLC, at the address set forth on the first page hereof, fax number (212) 312-6761, Attention: General Counsel, and if sent to the Company, to the address set forth on the first page hereof, fax number, _____Attention: _____. Notices sent by certified mail shall be deemed received five days thereafter, notices sent by hand delivery or overnight delivery shall be deemed received on the date of the relevant written record of receipt, and notices delivered by fax shall be deemed received as of the date and time printed thereon by the fax machine.

K. Miscellaneous. This Agreement shall not be modified or amended except in writing signed by Benchmark and the Company. This Agreement shall be binding upon and inure to t benefit of both Benchmark and the Company and their respective assigns, successors, and legal representatives. This Agreement constitutes the entire agreement of Benchmark and the Company, and supersedes any prior agreements, with respect to the subject matter hereof. If any provision of this Agreement is determined to be invalid or unenforceable in any respect, such determination will not affect such provision in any other respect, and the remainder of the Agreement shall remain in full force and effect. This Agreement may be executed in counterparts (including facsimile counterparts), each of which shall be deemed an original but all of which together shall constitute one and the same instrument.

In acknowledgment that the foregoing correctly sets forth the understanding reached by and between Benchmark and the Company, please sign in the space provided below, whereupon this letter shall constitute a binding Agreement as of the date indicated above.

Very truly yours,

THE BENCHMARK COMPANY

By: /s/ John J. Borer, III
Name: John J. Borer, III
Title: Managing Director

Accepted and Agreed:

Mana Capital Acquisition Corp.

By /s/ Jonathan Intrater
Name: Jonathan Intrater
Title: CEO

EXHIBIT 10.19

AMENDMENT NO. 1 ENGAGEMENT LETTER

Amendment 1 dated November 14, 2022 (this "**Amendment**") to the Engagement Letter dated as of May 13, 2022 between **The Benchmark Company,** LLC ("**Benchmark**") and **Cardio Diagnostics, Inc. [sic]** ("**Company**").

WHEREAS, the parties entered into an engagement letter dated as of May 13, 2022 (the "**Engagement Letter**") pursuant to which Benchmark agreed to act as the exclusive financial advisor in connection with a transaction or a related series or combination of transactions to the Company (as such terms are defined in the Engagement Letter) and

WHEREAS, Benchmark and the Company desire to amend the terms of the Engagement Letter as set forth below.

NOW THEREFORE, IT IS AGREED as follows:

1. Paragraphs A1, of the Engagement Letter is hereby deleted in its entirety and replaced with the following:

   A1 M&A Transaction Related Fee. If an M&A Transaction is effected during the Term (as hereafter defined) or the Tail Period (as hereafter defined), with a company, firm, entity or person with whom Benchmark had substantive discussions, correspondence or meetings on behalf of the Company (including any affiliates of any such parties), the Company shall pay Benchmark a cash fee for its services hereunder (the "Advisory Fees") equal (a) $ to $230,000 upon the close of the Transaction; plus (b) $435,000 payable 12 months from the date of the close of the Transaction.

2. A new paragraph Paragraphs A2 is added to the Engagement Letter as set out below.:

   A2. Right of First Refusal. For Twelve Months after the close of the Company's business combination with Cardio Diagnostics, Inc. (the "Transaction") the Company will offer Benchmark the right to act as lead or joint-lead investment banker, lead or joint-lead book-runner and/or lead or joint-lead placement agent, for each and every future public and private equity and debt offering, including all equity linked financings for the Company, or any successor to or any subsidiary of the Company as of such time, in connection with a financing to be conducted with accredited investors or institutions in the United States on customary terms (the "Right of First Refusal");In addition should the Company in the same Twelve Month period require a financial advisor, a Merger & Acquisitions advisor, a fairness opinion or any other transaction where the Company would engage the services of an investment banking firm to advise or assist it the Company shall also offer such a Right of First Refusal to Benchmark. The terms and conditions relating to any such engagement will be set forth in a separate engagement letter, agency agreement or underwriting agreement and the fees for such services will be in addition to the fees payable hereunder, will be negotiated separately and in good faith and will be consistent with fees paid to investment banks for similar services. If Benchmark does not accept the terms and conditions contained in the Company's offer, the Company may engage any other financial institution as lead or joint-lead investment banker, lead or joint-lead book runner and/or lead or joint-lead placement agent in connection with such transaction; provided, that the terms and conditions of any such engagement shall be no more favorable to such other financial institution as the terms and conditions offered by the Company to Benchmark. In addition, in the event that the Company receives, during such twelve month period, a third party offer to act as lead or joint-lead investment banker, lead or joint-lead book-runner and/or lead or joint-lead placement agent in connection with any offering of equity or convertible debt securities of the Company other than the Offering (including any such offering undertaken by the Company in connection with a liquidity event), the Company shall promptly give notice in writing to Benchmark of the particulars of the third party offer and Benchmark, for a period of five (5) business days from the date of receipt of such notice, shall have the right to match the terms of such third party offer, failing which, Benchmark shall relinquish its Right of First Refusal provided hereunder.

3. **No other Amendments.** Except as specifically provided herein, there are no other amendments to the Engagement Letter and all references to the Engagement Letter after the date hereof shall mean the Engagement Letter as modified by this Amendment.

4. **Signatures.** This Amendment may be executed in several counterparts or by separate instruments and all of such counterparts and instruments shall constitute one agreement, binding on all of the parties hereto.

5. **Defined Terms.** Capitalized terms used herein without definition shall have the respective meanings assigned to such terms in the Engagement Letter.

[*Signature Page to Follow]*

IN WITNESS WHEREOF, the parties have duly executed this Amendment as of the date first set forth above.

Very truly yours,

THE BENCHMARK COMPANY

By: /s/ John J. Borer, III
Name: John J. Borer, III
Title: Managing Director

Accepted and Agreed:

Mana Capital Acquisition Corp.

By /s/ Jonathan Intrater
Name: Jonathan Intrater
Title: CEO

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-8 (No. 333-270752) of Cardio Diagnostics Holdings, Inc. (the "Company"), of our report dated March 31, 2023, relating to the consolidated financial statements of the Company, appearing in this Annual Report on Form 10-K of the Company for the year ended December 31, 2022.

/s/ Prager Metis CPA's LLC

Hackensack, NJ
March 31, 2023

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, 2022 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: March 31, 2023

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, 2022 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: March 31, 2023

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, 2022, 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: March 31, 2023

/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)