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

FORM 10-Q

(Mark One)

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

For the quarterly period ended September 30, 2024

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

For the transition period from _____to _____

Commission File Number: 001-41097

Cardio Diagnostics Holdings, Inc.
(Exact name of registrant as specified in its charter)

Delaware	**87-0925574**
(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification No.)
311 West Superior Street, Suite 444 Chicago, Illinois	**60654**
(Address of principal executive offices)	(Zip Code)

(855) 226-9991
(Registrant's telephone number, including area code)

(Former name or former address, if changed since last report)

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

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

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

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

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

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

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

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

As of November 13, 2024, there were 40,439,810 shares of the registrant's Common Stock, $0.00001 par value, issued and outstanding.

CARDIO DIAGNOSTICS HOLDINGS, INC.

FORM 10-Q
For the Quarter Ended September 30, 2024

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INTRODUCTORY NOTE

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

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

SPECIAL NOTE ABOUT FORWARD-LOOKING STATEMENTS

This Quarterly Report on Form 10-Q contains "forward-looking statements" within the meaning of Section 27A of the Securities Act of 1933, as amended (the "Securities Act"), and Section 21E of the Securities Exchange Act of 1934, as amended (the "Exchange Act"). All statements other than statements of historical fact are "forward-looking statements" for purposes of federal and state securities laws, including, but not limited to, changes in laws or regulations, any statements about our business (including the impact on our business of a re-emergence of COVID-19 variants or any other pandemic, epidemic or infectious disease outbreak), financial condition, operating results, plans, objectives, expectations and intentions, any guidance on, or projections of, earnings, revenue or other financial items, or otherwise, and our future liquidity, including cash flows; any statements of any plans, strategies, and objectives of management for future operations, such as the material opportunities that we believe exist for our Company; any statements concerning proposed products and services, developments, mergers or acquisitions; or strategic transactions; any statements regarding management's view of future expectations and prospects for us; any statements about prospective adoption of new accounting standards or effects of changes in accounting standards; any statements regarding future economic conditions or performance; any statements of belief; any statements of assumptions underlying any of the foregoing; and other statements that are not historical facts. Forward-looking statements may be identified by the use of forward-looking terms such as "anticipate," "could," "can," "may," "might," "potential," "predict," "should," "estimate," "expect," "project," "believe," "think," "plan," "envision," "intend," "continue," "target," "seek," "contemplate," "budgeted," "will," "would," and the negative of such terms, other variations on such terms or other similar or comparable words, phrases, or terminology. These forward-looking statements present our estimates and assumptions only as of the date of this Quarterly Report on Form 10-Q and are subject to change.

Forward-looking statements involve risks and uncertainties and are based on the current beliefs, expectations, and certain assumptions of management. Some or all of such beliefs, expectations, and assumptions may not materialize or may vary significantly from actual results. Such statements are qualified by important economic, competitive, governmental, and technological factors that could cause our business, strategy, or actual results or events to differ materially from those in our forward-looking statements. Factors that might cause or contribute to such differences include, but are not limited to, the risk factors discussed under the heading "Risk Factors" in Part I, Item IA of our Annual Report on Form 10-K for the year ended December 31, 2023, filed with the Securities and Exchange Commission ("SEC") on April 1, 2024 (the "2023 Form 10-K"), Part II, Item 1A of our Quarterly Report on Form 10-Q for the three months ended March 31, 2024 filed with the SEC on May 15, 2024 (the "March 31, 2024 Form 10-Q"), Part II, Item 1A of our Quarterly Report on Form 10-Q for the three and six months ended June 30, 2024 filed with the SEC on August 12, 2024 (the "June 30, 2024 Form 10-Q") and in Part II, Item 1A of this Form 10-Q. Although we believe that the expectations reflected in our forward-looking statements are reasonable, actual results could differ materially from those projected or assumed in any of our forward-looking statements. Our future financial condition and results of operations, as well as any forward-looking statements, are subject to change, and significant risks and uncertainties that could cause actual conditions, outcomes, and results to differ materially from those indicated by such statements. Consequently, all of the forward-looking statements made in this Form 10-Q are qualified by these cautionary statements and there can be no assurance that the actual results or developments anticipated by the Company will be realized or, even if substantially realized, that they will have the expected consequence to or effects on the Company or its business or operations. The Company assumes no obligations to update any such forward-looking statements.

PART I: FINANCIAL INFORMATION

ITEM 1. FINANCIAL STATEMENTS

CARDIO DIAGNOSTICS HOLDINGS, INC.
CONSOLIDATED BALANCE SHEETS
(unaudited)

	September 30, 2024	December 31, 2023
ASSETS		
Current assets		
Cash	$ 1,982,590	$ 1,283,523
Accounts receivable	14,100	4,960
Prepaid expenses and other current assets	630,482	1,477,197
Total current assets	2,627,172	2,765,680
Long-term assets		
Property and equipment, net	706,659	571,873
Right of use assets, net	473,984	575,227
Intangible assets, net	9,333	21,333
Deposits	12,850	12,850
Patent costs, net	651,463	515,402
Total assets	$ 4,481,461	$ 4,462,365
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities		
Accounts payable and accrued expenses	$ 74,808	$ 243,213
Lease liability - current	233,871	223,929
Finance agreement payable	—	374,000
Total current liabilities	308,679	841,142
Long-term liabilities		
Lease liability – long term	486,597	663,099
Total liabilities	795,276	1,504,241
Stockholders' equity		
Preferred stock, $.00001 par value; authorized - 100,000,000 shares; 0 shares issued and outstanding as of September 30, 2024 and December 31, 2023, respectively	—	—
Common stock, $.00001 par value; authorized - 300,000,000 shares; 30,336,010 and 20,540,409 shares issued and outstanding as of September 30, 2024 and December 31, 2023, respectively	303	205
Additional paid-in capital	24,918,407	17,326,299
Accumulated deficit	(21,232,525)	(14,368,380)
Total stockholders' equity	3,686,185	2,958,124
Total liabilities and stockholders' equity	$ 4,481,461	$ 4,462,365

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

CARDIO DIAGNOSTICS HOLDINGS, INC.
CONSOLIDATED STATEMENTS OF OPERATIONS
(unaudited)

	THREE MONTHS ENDED SEPTEMBER 30,		NINE MONTHS ENDED SEPTEMBER 30,	
	2024	2023	2024	2023
Revenue	$ 6,580	$ 10,030	$ 30,378	$ 11,755
Operating expenses				
Sales and marketing	52,059	34,067	144,240	115,226
Research and development	5,247	38,708	23,367	137,690
General and administrative expenses	1,353,439	1,376,644	6,697,857	5,444,920
Amortization	4,802	4,802	14,389	14,380
Total operating expenses	1,415,547	1,454,221	6,879,853	5,712,216
Loss from operations	(1,408,967)	(1,444,191)	(6,849,475)	(5,700,461)

Other income (expenses)				
Change in fair value of derivative liability	—	(31,033)	—	5,602,052
Interest income	280	283	843	767
Interest expense	(3,879)	(570,385)	(15,513)	(6,638,912)
Gain (loss) on extinguishment of debt	—	112,944	—	(251,351)
Total other income (expenses)	(3,599)	(488,191)	(14,670)	(1,287,444)
Loss before provision for income taxes	(1,412,566)	(1,932,382)	(6,864,145)	(6,987,905)
Provision for income taxes	—	—	—	—
Net loss	$ (1,412,566)	$ (1,932,382)	$ (6,864,145)	$ (6,987,905)
Basic and fully diluted income (loss) per common share:				
Net loss per common share	$ (0.06)	$ (0.16)	$ (0.30)	$ (0.66)
Weighted average common shares outstanding - basic and fully diluted	24,442,853	11,903,708	22,715,559	10,573,070

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

CARDIO DIAGNOSTICS HOLDINGS, INC.
CONSOLIDATED STATEMENTS OF CHANGES IN STOCKHOLDERS' EQUITY
Three and Nine Months Ended September 30, 2024 and 2023
(unaudited)

	Common stock		Additional Paid-in	Accumulated	
	Shares	Amount	Capital	Deficit	Totals
Balances, December 31, 2023	20,540,409	$ 205	$ 17,326,299	$ (14,368,380)	$ 2,958,124
Common stock issued for cash	1,048,876	11	1,877,846	—	1,877,857
Restricted stock awards vested	39,689	—	58,000	—	58,000
Placement agent fee	—	—	(155,000)	—	(155,000)
Compensation for vested stock options	—	—	2,461,404	—	2,461,404
Net loss	—	—	—	(4,163,584)	(4,163,584)
Balances, March 31, 2024	21,628,974	$ 216	$ 21,568,549	$ (18,531,964)	$ 3,036,801
Common stock issued for cash	1,674,654	17	1,298,682	—	1,298,699
Restricted stock awards vested	9,442	—	6,000	—	6,000
Compensation for vested stock options	—	—	20,731	—	20,731
Net loss	—	—	—	(1,287,995)	(1,287,995)
Balances, June 30, 2024	23,313,070	$ 233	$ 22,893,962	$ (19,819,959)	$ 3,074,236
Common stock issued for cash	7,004,194	70	2,001,827	—	2,001,897
Restricted stock awards vested	18,746	—	6,000	—	6,000
Compensation for vested stock options	—	—	16,618	—	16,618
Net loss	—	—	—	(1,412,566)	(1,412,566)
Balances, September 30, 2024	30,336,010	$ 303	$ 24,918,407	$ (21,232,525)	$ 3,686,185
Balances, December 31, 2022	9,514,743	$ 95	$ 10,293,159	$ (5,991,546)	$ 4,301,708
Warrants converted to common stock	100,000	1	389,999	—	390,000
Restricted stock awards vested	1,092	—	4,000	—	4,000
Placement agent fee	—	—	(315,000)	—	(315,000)

Adjustment to liabilities assumed in merger with Mana	—	—	74,025	—	74,025
Net loss	—	—	—	(1,032,618)	(1,032,618)
Balances, March 31, 2023	9,615,835	$ 96	$ 10,446,183	$ (7,024,164)	$ 3,422,115
Restricted stock awards vested	87,917	1	105,999	—	106,000
Notes payable converted to common stock	1,474,703	15	2,368,026	—	2,368,041
Compensation for vested stock options	—	—	1,035,273	—	1,035,273
Net loss	—	—	—	(4,022,905)	(4,022,905)
Balances, June 30, 2023	11,178,455	$ 112	$ 13,955,481	$ (11,047,069)	$ 2,908,524
Restricted stock awards vested	177,807	2	71,998	—	72,000
Notes payable converted to common stock	1,761,063	17	1,239,572	—	1,239,589
Net loss	—	—	—	(1,932,382)	(1,932,382)
Balances, September 30, 2023	13,117,325	$ 131	$ 15,267,051	$ (12,979,451)	$ 2,287,731

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

CARDIO DIAGNOSTICS HOLDINGS, INC.
CONSOLIDATED STATEMENTS OF CASH FLOWS
(unaudited)

	Nine Months Ended September 30,	
	2024	2023
CASH FLOWS FROM OPERATING ACTIVITIES:		
Net loss	$ (6,864,145)	$ (6,987,905)
Adjustments to reconcile net loss to net cash used in operating activities		
Depreciation	76,341	1,377
Amortization	115,632	48,426
Stock-based compensation expense	2,568,753	1,217,273
Non-cash interest expense	—	6,612,298
Change in fair value of derivative liability	—	(5,602,052)
Loss on extinguishment of debt	—	251,351
Changes in operating assets and liabilities:		
Accounts receivable	(9,140)	(350)
Prepaid expenses and other current assets	846,715	876,066
Deposits	—	(7,900)
Accounts payable and accrued expenses	(168,405)	(401,638)
Lease liability	(166,560)	6,556
NET CASH USED IN OPERATING ACTIVITIES	(3,600,809)	(3,986,498)
CASH FLOWS FROM INVESTING ACTIVITIES:		
Purchases of property and equipment	(211,127)	(38,610)
Payments for right of use asset	—	(21,352)
Patent costs incurred	(138,450)	(167,381)
NET CASH USED IN INVESTING ACTIVITIES	(349,577)	(227,343)
CASH FLOWS FROM FINANCING ACTIVITIES:		
Proceeds from convertible notes payable, net of original issue discount of $ 500,000	—	4,500,000
Proceeds from exercise of warrants	—	390,000
Payments of placement agent fee	(155,000)	(315,000)
Proceeds from sale of common stock and warrants	5,178,453	—
Payments of finance agreement	(374,000)	(849,032)
NET CASH PROVIDED BY FINANCING ACTIVITIES	4,649,453	3,725,968
NET INCREASE (DECREASE) IN CASH	699,067	(487,873)
CASH - BEGINNING OF PERIOD	1,283,523	4,117,521
CASH - END OF PERIOD	$ 1,982,590	$ 3,629,648

SUPPLEMENTAL DISCLOSURES OF CASH FLOW INFORMATION:		
Cash paid during the period for:		
Interest	$ 15,513	$ 26,613
Income taxes	$ —	$ —
Non-cash investing and financing activities:		
Debt discount related to derivative liability	$ —	$ 5,000,000
Notes payable converted to common stock	$ —	$ 3,300,000
Adjustment to liabilities assumed in acquisition	$ —	$ 74,025
Right of use asset added to operating lease	$ —	$ 642,523

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

CARDIO DIAGNOSTICS HOLDINGS, INC.
NOTES TO CONSOLIDATED
FINANCIAL STATEMENTS
(UNAUDITED)

Note 1 - Organization and Basis of Presentation

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

Interim Financial Statements

The following (a) consolidated balance sheet as of December 31, 2023, which has been derived from audited financial statements, and (b) the unaudited consolidated interim financial statements of the Company as of and for the period ended September 30, 2024 have been prepared in accordance with the instructions to Form 10-Q and Rule 8-03 of Regulation S-X. Accordingly, they do not include all of the information and footnotes required by GAAP for complete financial statements. In the opinion of management, all adjustments (consisting of normal recurring accruals) considered necessary for a fair presentation have been included. Operating results for the three and nine months ended September 30, 2024 are not necessarily indicative of results that may be expected for the year ending December 31, 2024. These unaudited consolidated financial statements should be read in conjunction with the audited consolidated financial statements and notes thereto for the year ended December 31, 2023 included in the Company's Annual Report on Form 10-K, filed with the Securities and Exchange Commission ("SEC") on April 1, 2024.

Business Combination

On May 27, 2022, Mana, Mana Merger Sub, Inc. ("Merger Sub"), a wholly-owned direct subsidiary of Mana, Meeshanthini Dogan, the Shareholders' Representative, and Legacy Cardio entered into the Business Combination Agreement (the "Merger Agreement"). On October 25, 2022, pursuant to the Merger Agreement, Legacy Cardio merged with and into Merger Sub, with Legacy Cardio surviving as the wholly-owned subsidiary of Mana. Subsequent to the merger, Mana changed its name to Cardio Diagnostics Holdings, Inc.

Going Concern

The accompanying consolidated financial statements have been prepared on a going concern basis, which contemplates the realization of assets and the satisfaction of liabilities in the normal course of business. The Company has generated only nominal revenue in the past two years. The Company had a net loss of $6,864,145 for the nine months ended September 30, 2024 and an accumulated deficit of $ 21,232,525 at September 30, 2024. These factors, among others, raise substantial doubt about the ability of the Company to continue as a going concern for a reasonable period of time. The Company's continuation as a going concern is dependent upon its ability to obtain necessary equity financing and ultimately from generating revenues to continue operations. The Company expects that working capital requirements will continue to be funded through a combination of its existing funds and further issuances of securities. Working capital requirements are expected to increase in line with the growth of the business. Existing working capital, further advances and debt instruments, and anticipated cash flow are expected to be adequate to fund operations over the next twelve months. The Company has no lines of credit or other bank financing arrangements. Additional issuances of equity or convertible debt securities will result in dilution to current stockholders. Further, such securities might have rights, preferences or privileges senior to the Company's Common Stock. Additional financing may not be available upon acceptable terms, or at all. If adequate funds are not available or are not available on acceptable terms, the Company may not be able to take advantage of prospective new business endeavors or opportunities, which could significantly and materially restrict business operations.

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

CARDIO DIAGNOSTICS HOLDINGS, INC.
NOTES TO CONSOLIDATED
FINANCIAL STATEMENTS
(UNAUDITED)

Note 2 – Merger Agreement and Reverse Recapitalization

As discussed in Note 1, on October 25, 2022, the Company (formerly known as Mana) and Legacy Cardio entered into the Merger Agreement, which has been accounted for as a reverse recapitalization in accordance with GAAP. Pursuant to the Merger Agreement, the Company acquired cash of $4,021 and assumed liabilities of $928,500 from Mana. The liabilities assumed of $ 928,500 were payable to two investment bankers and due on October 25, 2023. The assumed liabilities decreased to $854,475, after net of an early payment discount of $ 74,025 issued by one of the two investment bankers on

March 22, 2023. On March 27, 2023, the Company accepted the early payment discount and paid Ladenburg the net balance due and payable of $419,475. On October 24, 2023, the Company paid the remaining post-merger liabilities balance of $ 435,000 to Benchmark.

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

As additional consideration for the transaction, Cardio may 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 Quarterly Report on Form 10-Q, the Company's common stock did not trade at equal to or greater than $12.50 for a period of at least 30 trading days out of 40 consecutive trading days and the Company has not issued any Earnout Shares.

Note 3 – Summary of Significant Accounting Policies

Principles of Consolidation

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

Use of Estimates in the Preparation of Financial Statements

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

Fair Value Measurements

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

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

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

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

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

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

The estimated fair value of the derivative liability was calculated using the Black-Scholes option pricing model. The Company uses Level 3 inputs to value its derivative liabilities. The following table provides a reconciliation of the beginning and ending balances for the major classes of assets and liabilities measured at fair value using significant unobservable inputs (Level 3) and reflects gains and losses for the nine months ended September 30, 2024 and 2023.

	2024	2023
Liabilities:		
Balance of derivative liabilities - beginning of period	$ —	$ —
Issued	—	9,192,672
Converted	—	(2,403,837)
Change in fair value recognized in operations	—	(5,602,052)
Balance of derivative liabilities - end of period	$ —	$ 1,186,783

The following table represents the Company's derivative instruments that are measured at fair value on a recurring basis as of September 30, 2024, for each fair value hierarchy level:

September 30, 2024	Derivative Liabilities	Total
Level I	$ —	$ —
Level II	$ —	$ —
Level III	$ —	$ —

Convertible Instruments

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

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

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

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

Revenue Recognition

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

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

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

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

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

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

1. Identifying the contract with a customer;

2. Identifying the performance obligations in the contract;

3. Determining the transaction price;

4. Allocating the transaction price to the performance obligations in the contract; and

5. Recognizing revenue when (or as) the Company satisfies its performance obligations.

Research and Development

Research and development costs are expensed as incurred. Research and development costs charged to operations for the nine months ended September 30, 2024 and 2023 were $23,367 and $137,690, respectively, and for the three months ended September 30, 2024 and 2023 were $ 5,247 and $38,708, respectively.

Advertising Costs

The Company expenses advertising costs as incurred. Advertising costs of $ 144,240 and $115,226 were charged to operations for the nine months ended September 30, 2024 and 2023, respectively, and of $52,059 and $34,067 for the three months ended September 30, 2024 and 2023, 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 September 30, 2024 and December 31, 2023. 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.

Property and Equipment and Depreciation

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

Office and computer equipment	5 years
Furniture and fixtures	7 years
Lab equipment	7 years
Leasehold improvements	7 years

Intangible Assets

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

Patent 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 evaluates its patents' estimated useful life and begins amortizing the patents when they are brought to the market or otherwise commercialized.

Impairment of Long-Lived Assets

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

Leases

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

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

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Stock-Based Compensation

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

Income Taxes

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

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

Recent Accounting Pronouncements

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

Note 4 – Property and Equipment

Property and equipment are carried at cost and consist of the following at September 30, 2024 and December 31, 2023:

	2024	2023
Office and computer equipment	$ 17,394	$ 17,394
Furniture and fixtures	96,818	76,099
Lab equipment	170,423	—
Leasehold improvements	502,155	482,170
Less: Accumulated depreciation	(80,131)	(3,790)
Total	$ 706,659	$ 571,873

Leasehold improvements of $502,155 represent costs of the buildout of the leased laboratory in Iowa City, Iowa that was completed in January 2024.

Depreciation expense of $76,341 and $1,377 was charged to operations for the nine months ended September 30, 2024 and 2023, respectively, and of $36,762 and $1,377 for the three months ended September 30, 2024 and 2023, respectively.

Note 5 – Intangible Assets

The following table provides details associated with the Company's acquired identifiable intangible assets at September 30, 2024 and December 31, 2023:

	2024	2023
Know-how license	$ 80,000	$ 80,000
Less: Accumulated amortization	(70,667)	(58,667)
Total	$ 9,333	$ 21,333

Amortization expense charged to operations was $12,000 for the nine months ended September 30, 2024 and 2023, respectively, and $ 4,000 for the three months ended September 30, 2024 and 2023, respectively.

Note 6 – Patent Costs

As of September 30, 2024, in the first family of patents and patent applications owned solely by UIRF and is exclusively licensed by Cardio, there are seven granted patents (US (2), EU, China, Australia, India and Hong Kong) and other pending patent applications. The Company has pending patent applications in patent families two, three, four and five. Legal fees associated with the patents totaled $651,463 and $515,402, net of accumulated amortization of $5,571 and $3,182 as of September 30, 2024 and December 31, 2023, respectively and are presented in the consolidated balance sheets as patent costs. Patents are amortized over their estimated useful lives of approximately 14 and 15 years, respectively. Amortization expense charged to operations was $2,389 and $2,380 for the nine months ended September 30, 2024 and 2023, respectively, and $ 802 for the three months ended September 30, 2024 and 2023, respectively.

Note 7 – Operating Leases

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

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

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

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

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

During the year ended December 31, 2023, the Company recorded ROU assets of $ 663,875 and operating lease liabilities of $642,523 at the lease commencement date. The discount rate used to determine the present value is the incremental borrowing rate, estimated to be 4.57% for the Chicago

lease and 4.24% for the Iowa City lease, respectively, as the interest rate implicit in our lease is not readily determinable.

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As of September 30, 2024 and December 31, 2023, operating lease ROU assets and operating lease liabilities are recorded on the consolidated balance sheets as follows:

	September 30, 2024	December 31 2023
Operating Lease:		
Operating lease right-of-use assets, net	$ 473,984	$ 575,227
Current portion of operating lease liabilities	$ 233,871	$ 223,929
Operating lease liabilities, net of current portion	$ 486,597	$ 663,099

As of September 30, 2024, the weighted-average remaining lease terms of the two operating leases were 2.2 years and 4.2 years, respectively.

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

2024 (remaining period)	$ 64,827
2025	260,611
2026	250,152
2027	102,060
2028	93,555
Total lease payments	771,205
Less: Imputed interest	50,737
Present value of lease liabilities	$ 720,468

At September 30, 2024, the Company had the following future minimum payments due under the non-cancelable lease:

2024 (remaining period)	$ 64,827
2025	260,611
2026	250,152
2027	102,060
2028	93,555
Total minimum lease payments	$ 771,205

Consolidated rental expense for all operating leases was $ 158,065 and $97,815 for the nine months ended September 30, 2024 and 2023, respectively, and $66,667 and $36,971 for the three months ended September 30, 2024 and 2023, respectively.

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The following table summarizes the cash paid and related right-of-use operating lease recognized for the nine months ended September 30, 2024.

	Nine months Ended September 30, 2024
Cash paid for amounts included in the measurement of lease liabilities:	
Operating cash flows from operating leases	$ 192,681
Right-of-use lease assets obtained in the exchange for lease liabilities:	
Operating leases	$ 166,560

Note 8 – Finance Agreement Payable

On October 25, 2023, the Company entered into an agreement with a premium financing company to finance its Directors and Officers insurance premiums for 12-month policies effective October 25, 2023. The amount financed of $467,500 is payable in 10 monthly installments plus interest at a rate of 8.95% through August 25, 2024. Finance agreement payable was $0 and $374,000 at September 30, 2024 and December 31, 2023, respectively. Accordingly, Directors and Officers insurance premiums of $550,000 has been recorded in prepaid expenses and is being amortized over the life of the policy until October 25, 2024, with unamortized balance of $36,164 and $449,041 as of September 30, 2024 and December 31, 2023, respectively.

Note 9 - Earnings (Loss) Per Common Share

The Company calculates net income (loss) per common share in accordance with ASC 260 “Earnings Per Share” (“ASC 260”). Basic and diluted net earnings (loss) per common share was determined by dividing net earnings (loss) applicable to common stockholders by the weighted average number of common shares outstanding during the period. The Company’s potentially dilutive shares, which include outstanding common stock options, common stock warrants, and convertible debt have not been included in the computation of diluted net loss per share for the nine months ended September 30, 2024 and 2023 as the result would be anti-dilutive.

	Nine months Ended September 30,	
	2024	2023

Stock warrants	8,528,766	7,854,620
Stock options	3,868,970	2,584,599
Total shares excluded from calculation	12,397,736	10,439,219

Note 10 – Stockholders' Equity

Stock Transactions

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

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

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

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

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

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

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

The 2022 Plan, as approved, permits the issuance of up to 3,265,516 shares of Common Stock (the "Share Reserve") upon exercise or conversion of grants and awards made from time to time to officers, directors, employees and consultants, however that the Share Reserve will increase on January 1st of each calendar year and ending on and including January 1, 2027 (each, an "Evergreen Date"), in an amount equal to the lesser of (i) 7% of the total number of shares of Common Stock outstanding on the December 31st immediately preceding the applicable Evergreen Date and (ii) such lesser number of shares of Common Stock as determined to be appropriate by the Compensation Committee, which administers the 2022 Plan, in its sole discretion. There was no increase in the Share Reserve on January 1, 2023. In January 2024, the Compensation Committee approved an annual increase in the Share Reserve of 1,060,458 shares.

Common Stock Issued

Private Placement

In connection with a private offering memorandum that the Company issued through a placement agent on January 23, 2024, the Company completed entering into subscription agreements with 7 accredited investors (the "Subscription Agreements"), whereby the Company issued a total of 561,793 units ("Units"), with each Unit consisting of (i) one share of the Company's common stock, $0.00001 par value (the "Common Stock"), and (ii) one six year Common Stock purchase warrant (the "Warrants"), having an exercise price of $1.78 per share (the "Private Placement"). The Private Placement resulted in the issuance to investors of 561,793 shares of Common Stock and 561,793 Warrants. The purchase price of the securities was $1.78 per Unit, resulting in gross proceeds to the Company of $1,000,000, before deducting placement agent fees (10% or $ 100,000) and other offering expenses. The Company intends to use the net proceeds from the Private Placement for working capital and general corporate purposes. The Private Placement closed on February 2, 2024.

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

At-the-Market Issuance

In connection with an At-the-Market Issuance Sales Agreement (the "Sales Agreement") that the Company entered into with a placement agent on January 26, 2024, the Company sold 9,165,931 shares of Common Stock at various amounts per share to investors for gross proceeds totaling $4,178,453 before deducting sales commissions of $104,446 to placement agent, during the nine months ended September 30, 2024 (among which 7,004,194 shares of Common Stock were sold for gross proceeds totaling $ 2,001,897 before deducting sales commissions of $50,047 to placement agent during the three months ended September 30, 2024). The Company also paid the placement agent a fee of $55,000.

Other Common Stock Issuance

During the three and nine months ended September 30, 2024, the Company issued 18,746 and 32,665 shares of Common Stock to two consultants for services pursuant to vesting of Restricted Stock Units granted, valued at $6,000 and $20,000, respectively.

On March 31, 2024, the Company issued 35,212 shares of Common Stock to the board of directors for services pursuant to vesting of Restricted Stock Units granted, valued at $50,000.

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

During the three and nine months ended September 30, 2023, the Company issued 30,747 and 35,724 shares of Common Stock to two consultants for services pursuant to vesting of Restricted Stock Units granted, valued at $22,000 and $32,000, respectively.

During the three and nine months ended September 30, 2023, the Company issued 147,060 and 231,092 shares of Common Stock to the board of directors for services pursuant to vesting of Restricted Stock Units granted, valued at $50,000 and $150,000 respectively.

In connection with the convertible notes payable (see Note 11 below) the noteholders converted $ 3,300,000 of principal balance to 3,235,766 shares of Common Stock during the nine months ended September 30, 2023 (among which principal balance of $1,150,000 was converted to 1,761,063 shares of Common Stock during the three months ended September 30, 2023). The number of shares of Common Stock issued was determined based on the terms of the convertible notes.

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 shares of Common Stock at the time of issuance. The warrant is exercisable on the earlier of the closing date of the next Qualified Equity Financing occurring after the issuance of the warrant, and immediately before a Change of Control. The exercise price is the price per share of the shares sold to investors in the next Qualified Equity Financing, or if the warrant becomes exercisable in connection with a Change in Control before the next Qualified Equity Financing, the greater of the quotient obtained by dividing $150,000 by the Pre-financing Capitalization, and the price per share paid by investors in the then-most recent Qualified Equity Financing, if any. The warrant will expire upon the earlier of the consummation of any Change of Control, or 15 years after the issuance of the warrant.

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

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

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

During the three and nine months ended September 30, 2024, in connection with the Private Placement as described above, the Company issued an aggregate of 0 and 674,146 warrants.

Warrant activity during the nine months ended September 30, 2024 and 2023 was as follows:

	Warrants Outstanding	Weighted Average Exercise Price	Weighted Average Remaining Contractual Life (Years)
Warrants outstanding at December 31, 2022	7,954,620	$ 9.63	4.46
Warrants exercised	(100,000)	3.90	
Warrants outstanding at September 30, 2023	7,854,620	$ 9.70	3.97
Warrants outstanding at December 31, 2023	7,854,620	$ 9.70	3.72
Warrants granted	674,146	1.78	
Warrants outstanding at September 30, 2024	8,528,766	$ 9.08	3.16

Options

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

On June 23, 2023, the Company granted 825,000 stock options to management, which vested immediately on grant date. Each option has an exercise price of $1.26 per share with an expiration date of June 23, 2033. These immediately vested stock options were valued at $1,035,273 at grant date based on the Black-Scholes Option Pricing model. The following assumptions were utilized in the Black-Scholes valuation of these immediately vested stock options during the nine months ended September 30, 2023, risk free interest rate of 5.41%, volatility of 176% and an exercise price of $1.26.

On January 23, 2024, the Company authorized an additional 1,060,458 shares to the Equity Incentive Plan Reserve (the "2022 Plan") and granted 1,187,826 options to management and employees, 1,166,826 of which vested immediately with the remaining 21,000 options subject to 50% vesting on June 30, 2024 and 100% vesting on December 31, 2024. Each option has an exercise price of $2.11 per share with an expiration date of

January 23, 2034. The immediately vested 1,166,826 stock options were valued at $2,461,404 at grant date based on the Black-Scholes Option Pricing model. The following assumptions were utilized in the Black-Scholes valuation of these immediately vested stock options during the nine months ended September 30, 2024, risk free interest rate of 5.22%, volatility of 228% and an exercise price of $2.11. For the remaining 21,000 options, 7,500 options were vested on June 30, 2024 and 8,500 options were forfeited before vesting with the leaving of the employees before September 30, 2024. The vested 7,500 stock options were valued at $4,106 at vesting date based on the Black-Scholes Option Pricing model. The following assumptions were utilized in the Black-Scholes valuation of these vested stock options during the nine months ended September 30, 2024, risk free interest rate of 4.40%, volatility of 188% and an exercise price of $2.11.

On June 30, 2024, the Company granted 30,300 stock options to the board of directors, which vested immediately on grant date. Each option has an exercise price of $0.55 per share with an expiration date of June 30, 2034. These immediately vested stock options were valued at $16,625 at grant date based on the Black-Scholes Option Pricing model. The following assumptions were utilized in the Black-Scholes valuation of these immediately vested stock options during the nine months ended September 30, 2024, risk free interest rate of 4.40%, volatility of 188% and an exercise price of $0.55.

On September 30, 2024, the Company granted 74,744 stock options to the board of directors, which vested immediately on grant date. Each option has an exercise price of $0.22 per share with an expiration date of September 30, 2034. These immediately vested stock options were valued at $16,618 at grant date based on the Black-Scholes Option Pricing model. The following assumptions were utilized in the Black-Scholes valuation of these immediately vested stock options during the three and nine months ended September 30, 2024, risk free interest rate of 3.79%, volatility of 184% and an exercise price of $0.22.

Option activity during the nine months ended September 30, 2024 and 2023 was as follows:

	Options Outstanding	Weighted Average Exercise Price	Weighted Average Remaining Contractual Life (Years)
Options outstanding at December 31, 2022	1,759,599	$ 3.90	9.35
Options granted	825,000	1.26	
Options outstanding at September 30, 2023	2,584,599	$ 3.06	8.97
Options outstanding at December 31, 2023	2,584,599	$ 3.06	8.71
Options granted	1,292,871	1.96	
Options expired or cancelled or forfeited	(8,500)	2.11	
Options outstanding at September 30, 2024	3,868,970	$ 2.69	7.72
Options vested and exercisable at September 30, 2024	3,863,970	$ 2.69	

Note 11 – Convertible Notes Payable

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

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

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

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

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

Note 12 – Derivative Liability

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

The Company used Level 3 inputs for its valuation methodology for the conversion option liability in determining the fair value using a Black-Scholes

option-pricing model with the following assumption inputs:

	Nine Months Ended September 30, 2023
Annual dividend yield	—
Expected life (years)	1.0
Risk-free interest rate	4.89% - 5.56%
Expected volatility	164% - 185%
Exercise price	$0.35 - $3.53
Stock price	$0.37 - $5.32

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

Note 13 – Commitments and Contingencies

Prior Relationship of Cardio with Boustead Securities, LLC

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

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

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

The Benchmark Company, LLC Right of First Refusal

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

Demand Letter and Potential Mootness Fee Claim

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

Northland Securities, Inc.

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

The Company cannot preclude the possibility that claims or lawsuits brought relating to any alleged securities law violations or breaches of fiduciary duty

could potentially require significant time and resources to defend and/or settle and distract its management and board of directors from focusing on its business.

Directors and Officers Insurance

In connection with the Company's various contractual obligations arising in the ordinary course of business, the Company is required to maintain insurance coverage for claims against its directors and officers.

Notice of Non-Compliance with Nasdaq Listing Requirements

On June 3, 2024, the Company received a letter from Nasdaq indicating that, for the previous 30 consecutive business days, the bid price for the Company's common stock had closed below the minimum $1.00 per share requirement for continued listing on Nasdaq under Nasdaq Listing Rule 5550(a)(2). As reported on our Current Report on Form 8-K dated June 7, 2024, we have an initial period of 180 calendar days, or until December 2, 2024 to regain compliance. Under certain circumstances, the Company may be granted an additional 180 days, or until May 29, 2025, to regain compliance. If we fail to regain compliance with the minimum bid requirement within the cure period (or extended cure period, if made available) or if we fail to continue to meet all applicable continued listing requirements for Nasdaq in the future, Nasdaq could delist our securities.

Note 14 – Subsequent Events

The Company evaluated its September 30, 2024 consolidated financial statements for subsequent events through the date the consolidated financial statements were issued.

Common Stock Issued

Subsequent to September 30, 2024, the Company sold 10,096,657 shares of Common Stock for gross proceeds totaling $ 2,596,434 under the At-the-Market Issuance Sales Agreement as of the date of this Report.

ITEM 2. 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.

The following discussion and analysis provide information that Cardio's management believes is relevant to an assessment and understanding of Cardio's results of operations and financial condition. You should read the following discussion and analysis of Cardio's results of operations and financial condition together with its unaudited consolidated financial statements and related notes to those statements included elsewhere in this Quarterly Report on Form 10-Q, and its audited consolidated financial statements and related notes to those statements included in the Company's 2023 Annual Report on Form 10-K that was filed on April 1, 2024 (the "2023 Form 10-K"). In addition to historical financial information, this discussion contains forward-looking statements based upon Cardio's current expectations that involve risks and uncertainties, including those described in the section titled, "Special Note About Forward-Looking Statements," above. Cardio's actual results could differ materially from such forward-looking statements as a result of various factors, including those set forth under "Risk Factors" in the 2023 Form 10-K (Item 1A therein), as well as in Part II, Item 1A of this Quarterly Report on Form 10-Q. Our historical results are not necessarily indicative of the results that may be expected for any period in the future.

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

Overview

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

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

Cardio launched its first clinical test, Epi+Gen CHD™, a three-year symptomatic CHD risk assessment clinical blood test targeting CHD events, including heart attacks, in 2021 during the Covid-19 pandemic. As a result, the initial strategy for commercialization involved launching the test via telemedicine and in smaller provider practices such as concierge medicine practices. The volume of tests through these channels were minimal, and as the circumstances around Covid-19 pandemic improved, management re-vamped the Company's go-to-market strategy to include other healthcare verticals and stakeholders beyond patients and small providers, including larger provider organizations, group purchasing organizations, employers, payors and life insurers. This new approach allowed Cardio to expand the reach of our solutions beyond the initial focus areas. Beyond the launch of Epi+Gen CHD, in March 2023, we announced the launch of our second product, PrecisionCHD™, an integrated epigenetic-genetic clinical blood test for the detection of coronary heart disease. The Epi+Gen CHD™ and PrecisionCHD™ tests are coupled to Actionable Clinical Intelligence ("ACI"), a platform that offers new epigenetic and genetic insights to clinicians prescribing the to help improve chronic care management. In May 2023, we launched CardioInnovate360™, a research-use-only ("RUO") solution to support the discovery, development and validation of novel biopharmaceuticals for the assessment and management of cardiovascular diseases. In February 2024, we announce the launch of HeartRisk™, a cardiovascular risk intelligence platform. We believe that our Epi+Gen CHD™ and PrecisionCHD™ tests are categorized as laboratory-developed tests, or "LDTs." The new go-to-market strategy is also being implemented for these products.

Despite long partnership and sales cycles, in some instance as long as 14 months, in 2023 Cardio generated revenue from patient(s), small provider(s), larger provider(s) and employer(s) for the first time and has developed a more robust sales and partnership pipeline. Key developments since the 2023 Form 10-K filing include:

- Increased revenue in the first nine months of 2024;
- Recommended pricing for our two Current Procedural Terminology (“CPT”) Proprietary Laboratory Analysis (“PLA”) codes from the American Medical Association, 0440U for PrecisionCHD™ and 0439U for Epi+Gen CHD™, at the Centers for Medicare and Medicaid Services’ (“CMS”) Clinical Laboratory Fee Schedule (CLFS) annual meeting; and
- Expanded the availability of our Epi+Gen CHD™ test to Family Medicine Specialists’ retail clinical location at Meijer Supercenter; and Received preliminary Medicare pricing from Centers for Medicare and Medicaid Services (CMS) for PrecisionCHD™ and Epi+Gen CHD™.

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

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

Recent Developments

Food and Drug Administration Proposed Regulation

On May 6, 2024, FDA published a final rule amending the definition of an in vitro diagnostic (“IVD”) device to include tests manufactured by a clinical laboratory. Pursuant to the rule, laboratory developed tests (“LDTs”), i.e., tests designed, manufactured, and used within a single CLIA-certified high complexity laboratory, are medical devices subject to FDA regulation under the Federal Food, Drug, and Cosmetic Act. The final rule also announced FDA’s intention to apply its medical device requirements to LDTs. Under the final rule, all LDTs, unless subject to a specific exemption, will be subject to premarket authorization requirements (510(k), de novo classification, or PMA) for each LDT performed by the laboratory, and to postmarket registration and listing, medical device reporting, correction, removal, and recall, complaint handling, labeling, investigational device, and quality system requirements. FDA intends to phase in these requirements beginning May 6, 2025. The final rule states that certain categories of LDTs will be subject to enforcement discretion with respect to some or all of these requirements. For example, FDA will apply enforcement discretion to currently marketed LDTs that were first offered prior to May 6, 2024, with respect to most quality system requirements and the requirement for premarket authorization if they are not modified or modified in only limited ways. Laboratories performing these tests are subject to other requirements, including the requirement to submit the labeling for the LDT to FDA for review. FDA will similarly exercise enforcement discretion with respect to premarket authorization for LDTs approved by the New York State Clinical Laboratory Evaluation Program (“NYS-CLEP”).

Unless overturned by a court or Congress, the final rule will substantially increase costs and regulatory burdens for many clinical laboratories in ways that may adversely affect their ability to develop, perform, and offer LDTs. Two lawsuits challenging FDA’s authority to regulate LDTs have been filed in federal court: the American Clinical Laboratory Association filed a lawsuit against FDA on May 29, 2024 in the Eastern District of Texas, while the Association for Molecular Pathology filed a lawsuit on August 19, 2024 in the Southern District of Texas. The lawsuits have been consolidated and briefing is expected to be completed by the end of 2024. The ultimate success of these lawsuits, or any future lawsuits that may be brought against the FDA challenging the LDT rule, is uncertain. It is also unclear whether a court would delay the implementation of the final rule while the litigation is ongoing, which means we may need to initiate steps to comply with the final rule even if it is ultimately overturned.

Legislative proposals addressing the FDA’s oversight of LDTs have been previously introduced. In June 2021, Congress introduced the VALID Act, which would have established a new risk-based regulatory framework for in vitro clinical tests (“IVCTs”), a category which would have included IVDs, LDTs, collection devices and instruments used with such tests. This legislation was not enacted during that session of Congress but was reintroduced in 2023. FDA’s new LDT final rule may renew attention to the VALID Act and may lead to the introduction of new proposals to limit the FDA’s regulatory authority. On July 12, 2024, the House Appropriations Committee issued a Report accompanying a FY 2025 appropriations bill in which it directed the FDA to suspend efforts to implement the LDT final rule and to continue working with Congress to modernize the regulatory approach for LDTs. This directive is not binding on the FDA.

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 Quarterly Report on Form 10-Q. The following table sets forth Cardio's results of operations data for the periods presented:

Comparisons for the three months ended September 30, 2024 and 2023:

The following table presents summary of consolidated operating results for the three-month periods indicated:

	Three Months Ended September 30,	
	2024	2023
Revenue		
Revenue	$ 6,580	$ 10,030
Operating Expenses		
Sales and marketing	52,059	34,067
Research and development	5,247	38,708
General and administrative expenses	1,353,439	1,376,644
Amortization	4,802	4,802
Total operating expenses	(1,415,547)	(1,454,221)
Other (expense) income	(3,599)	(488,191)
Net (loss)	$ (1,412,566)	$ (1,932,382)

Comparisons for the nine months ended September 30, 2024 and 2023:

The following table presents summary of consolidated operating results for the nine-month periods indicated:

	Nine Months Ended September 30,

	2024	2023
Revenue		
Revenue	$ 30,378	$ 11,755
Operating Expenses		
Sales and marketing	144,240	115,226
Research and development	23,367	137,690
General and administrative expenses	6,697,857	5,444,920
Amortization	14,389	14,380
Total operating expenses	(6,879,853)	(5,712,216)
Other (expense) income	(14,670)	(1,287,444)
Net (loss)	$ (6,864,145)	$ (6,987,905)

Net Loss

Cardio's net loss for the three months ended September 30, 2024 was $1,412,566 as compared to $1,932,382 for the three months ended September 30, 2023, a decrease of $519,816. The decrease in net loss was primarily the result of a decrease in interest expenses related to the sale and issuance of convertible debentures in 2023.

Cardio's net loss for the nine months ended September 30, 2024 was $6,864,145 as compared to $6,987,905 for the nine months ended September 30, 2023, a decrease of $123,760. The decrease in net loss was primarily the result of a decrease in interest expense related to the sale and issuance of convertible debentures in 2023, offset by an increase in operating expenses and a decrease in other income resulting from the change in fair value of derivative liability.

Revenue

Cardio had $6,580 and $10,030 in revenue for the three months ended September 30, 2024 and 2023, respectively.

Cardio had $30,378 and $11,755 in revenue for the nine months ended September 30, 2024 and 2023, respectively.

Sales and Marketing

Expenses related to sales and marketing for the three months ended September 30, 2024 were $52,059 as compared to $34,067 for the three months ended September 30, 2023, an increase of $17,992. The overall increase was due to an increase in sales and marketing activity in the third quarter of 2024 due to tradeshow attendance.

Expenses related to sales and marketing for the nine months ended September 30, 2024 were $144,240 as compared to $115,226 for the nine months ended September 30, 2023, an increase of $29,014. The overall increase was due to an increase in sales and marketing activity in the second and third quarters of 2024 due to tradeshow attendance.

Research and Development

Research and development expenses for the three months ended September 30, 2024 were $5,247 as compared to $38,708 for the three months ended September 30, 2023, a decrease of $33,461. The decrease was attributable to the decrease in laboratory runs performed in the 2024 period on new product offerings in the pipeline as compared to laboratory runs performed in the same period in 2023.

Research and development expenses for the nine months ended September 30, 2024 were $23,367 as compared to $137,690 for the nine months ended September 30, 2023, a decrease of $114,323. The decrease was attributable to the decrease in laboratory runs performed in the 2024 period on new product offerings in the pipeline as compared to laboratory runs performed in the same period in 2023.

General and Administrative Expenses

General and administrative expenses for the three months ended September 30, 2024 were $1,353,439 as compared to $1,376,644 for the three months ended September 30, 2023, remaining relatively the same with a small decrease of $23,205.

General and administrative expenses for the nine months ended September 30, 2024 were $6,697,857 as compared to $5,444,920 for the nine months ended September 30, 2023, an increase of $1,252,937. The overall increase is primarily due to an increase in stock compensation expenses of $1,351,480 (mainly as a result of new stock options issued in the first quarter of 2024), offset by the decrease in D&O insurance expense.

Amortization

Amortization expense was $4,802 for the three months ended September 30, 2024 and 2023. Amortization expense for each period consisted of expense for intangible assets of $4,000 and patent costs of $802, respectively.

Amortization expense for the nine months ended September 30, 2024 was $14,389 as compared to $14,380 for the nine months ended September 30, 2023. The total amortization expense for the nine months ended September 30, 2024 is for intangible assets of $12,000 and patent costs of $2,389, respectively, as compared to $12,000 for intangible assets and $2,380 for patent costs for the nine months ended September 30, 2023.

Other income (expenses)

Total other expenses for the three months ended September 30, 2024, was $(3,599) as compared to $(488,191) for the three months ended September 30, 2023. The total other expenses for the three months ended September 30, 2024 consists of interest expense of $3,879 net of interest income of $280. The total other expenses for the three months ended September 30, 2023 consists of change in fair value of derivative liability of $31,033, interest expense of $570,385 offset by gain on extinguishment of debt of $112,944 and interest income of $283.

Total other expenses for the nine months ended September 30, 2024, was $(14,670) as compared to $(1,287,444) for the nine months ended September 30, 2023. The total other expenses for the nine months ended September 30, 2024 consists of interest expense of $15,513 net of interest income of $843. The total other expenses for the nine months ended September 30, 2023 consists of interest expense of $6,638,912 and loss on extinguishment of debt of $251,351 offset by change in fair value of derivative liability of $5,602,052 and interest income of $767.

Liquidity and Capital Resources

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

Historically, our principal sources of liquidity have been proceeds from the issuance of equity. We entered into an At-the Market Sales Agreement with Craig-Hallum Capital Group LLC (“Craig-Hallum”) on January 26, 2024 (the “Sales Agreement”) under the terms of which we are able to sell up to $17.0 million of our Common Stock (the “ATM Offering”) from time to time and at our discretion. As of November 13, 2024, we have received an aggregate of $6,774,902 in gross proceeds from the ATM sales of 19,262,588 shares of Common Stock, and we have available up to $10,225,098 in future sales of our Common Stock that we may elect to make under the Sales Agreement. We have paid Craig-Hallum $169,373 in sales commissions as of November 13, 2024.

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

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 grow our business. We expect that our primary cash needs in 2024 and for the foreseeable future will be for funding day-to-day operations and working capital requirements, funding our growth strategy, paying the setup expenses of our internal laboratory and paying expenses incurred in connection with our ongoing FDA submission activities. We explore our financing options on an ongoing basis. However, given recent stock prices and the extreme volatility of our stock, it continues to be challenging to balance cash that could be raised and the dilution that might be required to close a particular transaction. We expect that for the remainder of 2024, we will rely primarily on the ongoing ATM Offering, provided that market conditions are favorable.

At our annual stockholders meeting in December 2023, we obtained stockholder approval to offer and sell up to $10,000,000 in securities (up to 50,000,000 shares of Common Stock, subject to adjustment for stock splits, reverse stock splits and other similar recapitalization events) in a transaction or series of transactions not involving a public offering. This authorization has expired. At our 2024 annual meeting scheduled for November 15, 2024, we plan to ask our stockholders to make available this potential future issuance of securities for a new three-month period together with the potential to obtain Nasdaq’s consent, which we cannot guarantee, for an additional three-month period thereafter, resulting in a possible six-month period to conduct a financing within the parameters of the stockholder authority, if granted. We currently have no specific plans for such future offering but believe having that option available provides our Board of Directors with added flexibility in meeting the Company’s liquidity needs.

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 expect this trend to continue in future periods for the foreseeable future.

Unless we are able to generate significant cash flows from operations, which we do not foresee happening in the near term, we will need to finance our operations through the issuance of additional equity and/or convertible debt securities. Looking forward, 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, particularly at current stock price levels, 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.

Working capital requirements are expected to increase in line with the growth of the business. We have no lines of credit or other bank financing arrangements. We anticipate that our principal sources of liquidity, including existing funds and issuances of equity and/or debt securities, will only be sufficient to fund our activities over the next 12 months. In order to have sufficient cash to fund our operations beyond the next 12 months and grow our business, we will need to raise additional funds through the issuance of equity or convertible debt. We cannot provide any assurance that we will be successful in doing so.

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 our business plan, balanced against ongoing expenses. There is no assurance that we will be successful in reaching and sustaining profitability.

The exercise prices of our currently outstanding warrants range from a high of $11.50 to a low of $1.78 (subject to adjustment) per share of Common Stock. 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 $0.36 on November 12, 2024. If the trading price of our Common Stock is less than the respective exercise prices of our outstanding Warrants, which has been the case for a substantial period of time, we believe holders of any of our 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 September 30, 2024 totaled $1,982,590 as compared to $1,283,523 at December 31, 2023, an increase of $699,067. The following table shows Cardio’s cash flows from operating activities, investing activities and financing activities for the stated periods:

	Nine Months ended September 30,	
	2024	2023
Net cash used in operating activities	$ 3,600,809	$ 3,986,498
Net cash used in investing activities	349,577	227,343
Net cash provided by financing activities	4,649,453	3,725,968

Cash Used in Operating Activities

Cash used in operating activities for the nine months ended September 30, 2024 was $3,600,809 as compared to $3,986,498 for the nine months ended September 30, 2023. The cash used in operations during the nine months ended September 30, 2024 is a function of net loss of $6,864,145 adjusted for

the following non-cash operating items: depreciation of $76,341, amortization of $115,632, $2,568,753 in stock-based compensation, an increase of $9,140 in accounts receivable, a decrease of $846,715 in prepaid expenses and other current assets, a decrease of $168,405 in accounts payable and accrued expenses and a decrease in lease liability of $166,560.

The cash used in operations during the nine months ended September 30, 2023 is a function of net loss of $6,987,905 adjusted for the following non-cash operating items: depreciation of $1,377, amortization of $48,426, $1,217,273 in stock based compensation, $6,612,298 in non-cash interest expense, and $251,351 for loss on extinguishment of debt offset by $5,602,052 in change in fair value of derivative liability, an increase of $350 in accounts receivable, a decrease of $876,066 in prepaid expenses and other current assets, an increase in deposits of $7,900, a decrease of $401,638 in accounts payable and accrued expenses and an increase in lease liability $6,556.

Cash Used in Investing Activities

Cash used in investing activities for the nine months ended September 30, 2024 was $349,577 compared to $227,343 for the nine months ended September 30, 2023. The cash used in investing activities for the nine months ended September 30, 2024 was due to purchases of property and equipment of $211,127 and patent costs incurred of $138,450. The cash used in investing activities for the nine months ended September 30, 2023 was due to purchases of property and equipment of $38,610, payments for right of use asset of $21,352 and patent costs incurred of $167,381.

Cash Provided by Financing Activities

Cash provided by financing activities for the nine months ended September 30, 2024 was $4,649,453 as compared to $3,725,968 for the nine months ended September 30, 2023. This change was due to $5,178,453 in proceeds from the sale of common stock and warrants offset by $374,000 in payments pursuant to a finance agreement and $155,000 in payments of placement agent fees, all of which occurred during the nine months ended September 30, 2024. Cash provided by financing activities for the nine months ended September 30, 2023 was due to $4,500,000 in proceeds from convertible notes payable, net of original issue discount of $500,000, $390,000 in proceeds from exercise of warrants, offset by $849,032 payments of finance agreement and $315,000 in payments of placement agent fees during the nine months ended September 30, 2023.

Going Concern

The accompanying consolidated financial statements have been prepared on a going concern basis, which contemplates the realization of assets and the satisfaction of liabilities in the normal course of business. The Company has generated only nominal revenue since inception. The Company had a net loss of $6,864,145 for the nine months ended September 30, 2024 and an accumulated deficit of $21,232,525 at September 30, 2024. These factors, among others, raise substantial doubt about the ability of the Company to continue as a going concern for a reasonable period of time. The Company's continuation as a going concern is dependent upon its ability to obtain necessary equity financing and ultimately from generating revenues to continue operations. The Company expects that working capital requirements will continue to be funded through a combination of its existing funds and further issuances of securities. Existing working capital, further advances and debt instruments, and anticipated cash flow are expected to be adequate to fund operations over the next twelve months. The Company has no lines of credit or other bank financing arrangements. Additional issuances of equity or convertible debt securities will result in dilution to current stockholders. Further, such securities might have rights, preferences or privileges senior to the Company's Common Stock. Additional financing may not be available upon acceptable terms, or at all. If adequate funds are not available or are not available on acceptable terms, the Company may not be able to take advantage of prospective new business endeavors or opportunities, which could significantly and materially restrict business operations.

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

Off-Balance Sheet Financing Arrangements

We did not have any off-balance sheet arrangements as of September 30, 2024.

Contractual Obligations

As of September 30, 2024, we do not have any ongoing contractual obligations that would have a negative impact on liquidity and cash flows. However, if one or more of the following potential claims that arise from contracts we have entered into were pursued against us, there is the potential that we could see a negative impact on liquidity and cash flows, depending on the outcome.

Prior Relationships of Cardio with Boustead Securities, LLC

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

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

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

The Benchmark Company, LLC Right of First Refusal

As noted in Note 1, the Company completed a business combination with Mana on October 25, 2022. In connection with the proposed business

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

Demand Letter and Potential Mootness Fee Claim

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

Northland Securities, Inc.

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

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

Directors and Officers Insurance

In connection with the Company's various contractual obligations arising in the ordinary course of business, the Company is required to maintain insurance coverage for claims against its directors and officers.

Notice of Non-Compliance with Nasdaq Listing Requirements

On June 3, 2024, the Company received a letter from Nasdaq indicating that, for the previous 30 consecutive business days, the bid price for the Company's common stock had closed below the minimum $1.00 per share requirement for continued listing on Nasdaq under Nasdaq Listing Rule 5550(a)(2). As reported on our Current Report on Form 8-K dated June 7, 2024, we have an initial period of 180 calendar days, or until December 2, 2024 to regain compliance. Under certain circumstances, the Company may be granted an additional 180 days, or until May 29, 2025, to regain compliance. If we fail to regain compliance with the minimum bid requirement within the cure period (or extended cure period, if made available) or if we fail to continue to meet all applicable continued listing requirements for Nasdaq in the future, Nasdaq could delist our securities.

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.

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)

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 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

Pursuant to Item 305(e) of Regulation S-K, the Company is not required to provide the information required by this Item as it is a "smaller reporting company."

ITEM 4. 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 the design and operation of our disclosure controls and procedures, as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act, as of the end of the period covered by this Quarterly Report. 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 are 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-Q 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.

Changes in Internal Control over Financial Reporting

There has not been any change in our internal control over financial reporting that occurred during the three and nine months ended September 30, 2024 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

PART II. OTHER INFORMATION

ITEM 1. LEGAL PROCEEDINGS

From time-to-time, the Company may be involved in various civil actions as part of its normal course of business. The Company is not a party to any litigation that is material to ongoing operations as defined in Item 103 of Regulation S-K as of the period ended September 30, 2024.

ITEM 1A. RISK FACTORS

There have been no material changes to the risk factors previously described in Item 1A of Part I of our Annual Report on Form 10-K for the fiscal year ended December 31, 2023 except as set forth below. These risk factors, collectively, describe some of the assumptions, risks, uncertainties and other factors that could adversely affect our business or that could otherwise result in changes that differ materially from our expectations. We may disclose changes to such risk factors or disclose additional risk factors from time to time in our future filings with the SEC, including as set forth below. Additional risks and uncertainties not currently known to us or that we currently deem to be immaterial also may materially adversely affect our business, financial condition or future results.

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

Our Common Stock is listed on The Nasdaq Capital Market ("Nasdaq"). In order to maintain that listing, we must satisfy minimum financial and other

requirements including, without limitation, a requirement that the closing bid price of our Common Stock be at least $1.00 per share. On June 3, 2024, we received a letter from Nasdaq indicating that, for the previous 30 consecutive business days, the bid price for the Company's common stock had closed below the minimum $1.00 per share requirement for continued listing on Nasdaq under Nasdaq Listing Rule 5550(a)(2). As reported on our Current Report on Form 8-K dated June 7, 2024, we have an initial period of 180 calendar days, or until December 2, 2024 to regain compliance. Under certain circumstances, we may be granted an additional 180 days, or until May 29, 2025, to regain compliance. We anticipate seeking Nasdaq's grant of the additional 180-day extension of the compliance deadline before December 2, 2024. If we fail to regain compliance with the minimum bid requirement within the cure period (or extended cure period, if made available) or if we fail to continue to meet all applicable continued listing requirements for Nasdaq in the future, Nasdaq could delist our securities.

If Nasdaq delists our shares of Common Stock and Public Warrants for failure to meet the listing standards, we and our securityholders could face significant material adverse consequences including:

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

Although our financial statements have been prepared on a going concern basis, we must raise additional capital to fund our operations in order to continue as a going concern.

Prager Metis, our independent registered public accounting firm for the fiscal year ended December 31, 2023, has included an explanatory paragraph in their opinion that accompanied our audited consolidated financial statements as of and for the year ended December 31, 2023, indicating that our current liquidity position raises substantial doubt about our ability to continue as a going concern. Disclosure in Management's Discussion and Analysis of Financial Condition and Results of Operations – Liquidity and Capital Resources in this Form 10-Q reiterates this risk as of the third quarter of 2024. If we are unable to improve our liquidity position, we may not be able to continue as a going concern. Our 2023 audited consolidated financial statements did not include any adjustments that might result if we are unable to continue as a going concern and, therefore, be required to realize our assets and discharge our liabilities other than in the normal course of business which could cause investors to suffer the loss of all or a substantial portion of their investment. We anticipate that our principal sources of liquidity will only be sufficient to fund our activities over the next 12 months. In order to have sufficient cash to fund our operations beyond the next 12 months, we will need to raise additional equity over the next 12 months in order to continue as a going concern and we cannot provide any assurance that we will be successful in doing so.

The U.S. Food and Drug Administration's ("FDA's") newly-issued rule for laboratory developed tests ("LDTs"), which will be phased in over a period of four years, will significantly change the regulatory landscape for LDTs. Unless the rule is overturned by a court or Congress, our currently marketed LDTs and those we develop in the future will be subject to new requirements which may include, for some tests, premarket clearance, de novo authorization or premarket approval. We will incur substantial costs and delays associated with complying with the new rule.

We believe our Epi+Gen CHD™ and PrecisionCHD™ tests are LDTs. The FDA generally considers an LDT to be a test that is designed, manufactured, and used within a single laboratory that is certified under CLIA and meets the regulatory requirements under CLIA to perform high complexity testing

The FDA has historically taken the position that it has the authority to regulate LDTs as in-vitro diagnostics ("IVDs") under the Federal Food, Drug, and Cosmetic Act ("FDC Act"), although it has generally exercised enforcement discretion with regard to LDTs. This means that even though the FDA believes it can impose regulatory requirements on LDTs, such as requirements to obtain premarket approval, de novo authorization or clearance of LDTs, it has generally chosen not to enforce those requirements.

On May 6, 2024, the FDA published a final rule amending the definition of an IVD device to include IVDs manufactured by a clinical laboratory. The final rule also announced the FDA's intention to phase out its general enforcement discretion policy. On May 29, 2024, the American Clinical Laboratory Association filed a lawsuit against FDA in the Eastern District of Texas challenging the FDA's agency authority to regulate LDTs. On August 19, 2024, the Association for Molecular Pathology filed a separate lawsuit in challenging FDA's authority the Southern District of Texas. These lawsuits have been consolidated and briefing is expected to be completed by the end of 2024.The ultimate success of these lawsuits, or any future lawsuits that may be brought against the FDA challenging the LDT rule, is uncertain. It is also unclear whether a court would delay the implementation of the final rule while the litigation is ongoing, which means we may need to initiate steps to comply with the final rule even if it is ultimately overturned. Unless the rule is overturned by a court or Congress, the medical device requirements for most LDTs will be phased in beginning on May 6, 2025.

The requirements established in the Final Rule include premarket authorization for some LDTs (510(k) clearance, de novo authorization or premarket approval) performed by a laboratory, and postmarket registration and listing, medical device reporting, correction, removal, and recall, complaint handling, labeling, investigational device, and quality system requirements. Certain categories of LDTs will be subject to enforcement discretion with respect to some or all of these requirements. For example, FDA will apply enforcement discretion to currently marketed LDTs that were first offered prior to May 6, 2024, with respect to most quality system requirements and the requirement for premarket authorization if they are not modified or modified in only limited ways. Laboratories performing these tests are subject to other requirements, including the requirement to submit the labeling for the LDT to FDA for review, which could be burdensome and expensive. FDA will similarly exercise enforcement discretion with respect to premarket clearance, de novo classification, or premarket approval requirements for LDTs approved by the New York State Clinical Laboratory Evaluation Program.

Compliance with these additional regulatory requirements will be time-consuming and expensive. If we are required to obtain premarket notification, de novo authorization or premarket approval for our existing tests, or for any future tests we may develop, we may be required to successfully complete analytical, pre-clinical and/or clinical studies beyond the studies we have already performed or planned to perform for our LDTs. 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 meet the FDA's requirements. The studies may also not be conducted in a manner that meets the FDA's requirements, and therefore may not support the marketing application. There can be no assurance that the submission of such an application will result in a timely response by the FDA or a favorable outcome that will allow the test to be marketed. In addition, we may be forced to stop selling our tests or we may be required to modify claims for or make other changes to our tests while we work to obtain FDA clearance approval or de novo authorization. Our business may be adversely affected while such review is ongoing and if we are ultimately unable to obtain premarket clearance. de novo authorization or premarket approval.

Various bills have been introduced in Congress seeking to substantially revamp the regulation of both LDTs and IVDs, but no legislation has been enacted thus far.

ITEM 2. UNREGISTERED SALES OF EQUITY SECURITIES AND USE OF PROCEEDS

None.

ITEM 3. DEFAULTS UPON SENIOR SECURITIES

None.

ITEM 4. MINE SAFETY DISCLOSURES

None.

ITEM 5. OTHER INFORMATION

During the quarter ended September 30, 2024, no director or officer adopted or terminated:

(i) Any contract, instruction or written plan for the purchase or sale of securities of the Company intended to satisfy the affirmative defense conditions of Rule 10b5-1(c); and

(ii) Any "non-Rule 10b5-1 trading arrangement" as defined in paragraph (c) of item 408(a) of Regulation S-K.

ITEM 6. EXHIBITS

The following exhibits are filed as part of, or incorporated by reference into, this Quarterly Report on Form 10-Q.

Exhibit Number	Description	Incorporation by Reference		
		Form	Exhibit	Filing Date
2.1	Agreement and Plan of Merger dated as of May 27, 2022 by and among Mana Capital Acquisition Corp., Mana Merger Sub, Inc., Cardio Diagnostics, Inc., and Meeshanthini (Meesha) Dogan, as representatives of the shareholders (included as Annex A to the Proxy Statement/Prospectus)	8-K	2.1	5/31/2022
2.2	Amendment dated September 15, 2022 to Agreement and Plan of Merger dated as of May 27, 2022 by and among Mana Capital Acquisition Corp., Mana Merger Sub, Inc., Cardio Diagnostics, Inc., and Meeshanthini (Meesha) Dogan, as representatives of the shareholders	8-K	2.1	9/15/22
2.3	Waiver Agreement dated as of October 25, 2022 with respect to Agreement and Plan of Merger dated as of May 27, 2022, as amended on September 15, 2022	8-K	2.3	10/31/22
3.1	Third Amended and Restated Certificate of Incorporation of Cardio Diagnostics Holdings, Inc., dated May 30, 2023	8-K	3.1	5/30/23
3.2	By-laws	S-1	3.3	10/19/21
4.1	Specimen Stock Certificate	S-1/A	4.2	11/10/21
4.2	Specimen Warrant Certificate (contained in Exhibit 4.3)	8-K	4.1	11/26/21
4.3	Warrant Agreement, dated November 22, 2021, by and between the Company and Continental Stock Transfer & Trust Company, as warrant agent	8-K	4.1	11/26/21
4.4	Description of Securities	10-K	4.5	4/1/24
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 pursuant to 18 U.S. C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002			
32.2+	Certification of 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.

+ Furnished herewith. The certifications attached as Exhibit 32.1 and Exhibit 32.2 that accompany this Quarterly Report on Form 10-Q are deemed furnished and not filed with the Securities and Exchange Commission and are 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 Quarterly Report on Form 10-Q, irrespective of any general incorporation language contained in such filing.

SIGNATURES

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

Cardio Diagnostics Holdings, Inc.

Date: November 13, 2024

By: /s/ Elisa Luqman
Elisa Luqman
Chief Financial Officer

EXHIBIT 31.1

CERTIFICATION

I, Meeshanthini V. Dogan, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of Cardio Diagnostics Holdings, Inc. for the quarter ended September 30, 2024;

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 and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

(a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

(b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

(c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

(d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer 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.

Dated: November 13, 2024

/s/ Meeshanthini V. Dogan

Meeshanthini V. Dogan
Chief Executive Officer
(Principal Executive Officer)

EXHIBIT 31.2

CERTIFICATION

I, Elisa Luqman, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of Cardio Diagnostics Holdings, Inc. for the quarter ended September 30, 2024;

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 and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

(a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

(b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

(c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

(d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer 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.

Dated: November 13, 2024

/s/ Elisa Luqman

Elisa Luqman
Chief Financial Officer
(Principal Financial and Accounting 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 this Quarterly Report on Form 10-Q, (the "Report") of Cardio Diagnostics Holdings, Inc. (the "Company") for the quarter ended September 30, 2024, the undersigned, Meeshanthini V. Dogan, hereby certifies pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that, to the best of the undersigned's knowledge and belief:

(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.

Dated: November 13, 2024

/s/ Meeshanthini V. Dogan

Meeshanthini V. Dogan
Chief Executive Officer
(Principal Executive Officer)

EXHIBIT 32.2

CERTIFICATION PURSUANT TO 18 U.S.C. SECTION 1350,

AS ADOPTED PURSUANT TO SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with this Quarterly Report on Form 10-Q, (the "Report") of Cardio Diagnostics Holdings, Inc. (the "Company") for the quarter ended September 30, 2024, the undersigned, Elisa Luqman, hereby certifies pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that, to the best of the undersigned's knowledge and belief:

(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.

Date: November 13, 2024

By: /s/ Elisa Luqman
Elisa Luqman
Chief Financial Officer