



DIVISION OF  
CORPORATION FINANCE

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

April 24, 2025

Elisa Luqman  
Chief Financial Officer  
Cardio Diagnostics Holdings, Inc.  
311 West Superior Street Suite 444  
Chicago, IL 60654

**Re: Cardio Diagnostics Holdings, Inc.**  
**Form 10-K for the Fiscal Year Ended December 31, 2024**  
**File No. 001-41097**

Dear Elisa Luqman:

We have limited our review of your filing to the financial statements and related disclosures and have the following comments.

Please respond to this letter within ten business days by providing the requested information or advise us as soon as possible when you will respond. If you do not believe a comment applies to your facts and circumstances, please tell us why in your response.

After reviewing your response to this letter, we may have additional comments.

Form 10-K for the Fiscal Year Ended December 31, 2024

Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations  
Recent Regulatory Developments, page 59

1. We note your disclosure that beginning on May 6, 2025, unless overturned by a court or Congress or stayed or withdrawn by the new Administration, implementation of the FDA final rule on laboratory developed tests will "substantially increase costs and regulatory burdens" for many clinical laboratories. Please revise your disclosure in future filings to describe the potential material unfavorable impact that implementation of this new law is reasonably likely to have on your net sales or revenues or income from continuing operations. Refer to Item 303(b)(2)(ii) of Regulation S-K.

General and Administrative Expenses, page 61

2. We note your general and administrative expenses represent over 80% of net loss for 2024 and 2023. Please revise your future filings to disaggregate your general and

administrative expenses to provide investors with a quantified understanding of significant underlying components that are material to your operations. Your current disclosures only provide explanation of the year-over-year change and the nature and drivers of current year activity are unclear. Further, enhance your disclosures to clarify the impact of material changes on future operating trends. Refer to Item 303(b)(2) of Regulation S-K.

Contractual Obligations, page 64

3. We note that it appears you are contractually obligated under your exclusive license agreement with the University of Iowa Research Foundation ("UIRF"), entered into on May 2, 2017 and amended on September 2, 2022, to pay each of: (i) 2% of annual net sales, and (ii) 15% of non-royalty fees to UIRF if the Company enters into one or more sublicensing agreements. Please revise your future contractual obligation disclosures to include a discussion of your license agreements to disclose all material payment terms including quantification of any amounts the Company has paid under such agreements to date, as well as term and termination provisions.

Item 9A. Controls and Procedures, page 67

4. We note your annual report does not include a report of management's assessment regarding internal control over financial reporting ("ICFR") due to a transition period established by rules of the Securities and Exchange Commission for newly public companies. Since you were required to file or filed an annual report for the prior year, it appears you are required to report on your management's assessment of ICFR. Please confirm that you will revise your future filings to provide management's conclusion regarding the effectiveness of your internal control over financial reporting. Refer to Item 308(a) of Regulation S-K.

Item 8. Financial Statements and Supplemental Data

Note 3 - Summary of Significant Accounting Policies, page F-7

5. Please confirm that you will provide the segment disclosures required by ASC 280-10-50, as amended by ASU 2023-07, in your future filings. Refer to ASC 280-10-50-20 for single reportable segment entity requirements.

In closing, we remind you that the company and its management are responsible for the accuracy and adequacy of their disclosures, notwithstanding any review, comments, action or absence of action by the staff.

Please contact Bonnie Baynes at 202-551-4924 or Angela Connell at 202-551-3426 with any questions.

Sincerely,

Division of Corporation Finance  
Office of Life Sciences