Onconetix, Inc.
201 E. Fifth Street, Suite 1900
Cincinnati, OH 45202

VIA EDGAR

June 13, 2024

U.S. Securities and Exchange Commission
Division of Corporation Finance
Office of Life Sciences
Washington, D.C. 20549

Attention: Tara Harkins
Angela Connell
Jimmy McNamara
Jason Drory

Re: Onconetix, Inc.
Amendment No. 1 Registration Statement on Form S-1
Filed February 14, 2024
File No. 333-277066

Ladies and Gentlemen:

Onconetix, Inc. (the "**Company**") hereby transmits its response to the comment letter received from the staff (the "**Staff**") of the U.S. Securities and Exchange Commission (the "**Commission**") on May 10, 2024, relating to Amendment No. 1 to the Registration Statement on Form S-1, submitted by the Company to the Commission on February 14, 2024 (the "**Registration Statement**").

For the Staff's convenience, we have repeated below the Staff's comments in bold and have followed each comment with the Company's response. Disclosure changes made in response to the Staff's comments have been made in Amendment No. 2 to the Registration Statement (the "**Amended Registration Statement**"), which is being submitted to the Commission contemporaneously with the submission of this letter.

Amendment No. 1 to Registration Statement on Form S-1 Prospectus Summary
Our Company, page 1

1. **We note your response to comment 4 and re-issue. Please revise the prospectus summary to clarify when the diagnostic was approved and describe the specific target market for Proclarix or otherwise advise. We note your disclosure on page 74 that "Proclarix is intended for use in diagnosing ["grey zone"] patients where it is difficult to decide if a biopsy is necessary to verify a potential clinically significant cancer diagnosis."**

   The Company respectfully acknowledges the Staff's comment and advises the Staff that it has amended its disclosure on pages 1-2 of the Registration Statement to include the requested information.

2. **Consistent with your disclosure on page 60, please update your disclosure here to quantify the approximate percentage ownership stake Proteomedix shareholders will have in Onconetix if the Series B Convertible Preferred Stock are converted into shares of common stock.**

   The Company respectfully acknowledges the Staff's comment and advises the Staff that it has amended its disclosure on page 2 of the Registration Statement to include the requested information

About this Offering Risk Factors, page 4

3. **We note your reference to "Incorporation of Certain Information by Reference," but this section appears to have been removed from this amendment. Please revise or otherwise advise.**

The Company respectfully acknowledges the Staff's comment and advises the Staff that it has amended its disclosure on page 157 of the Registration Statement to include the requested information.

Risk Factors, page 5

4. **Please provide concise, bulleted or numbered statements that is no more than two pages summarizing your principal risk factors. Refer to Item 105(b) of Regulation S-K.**

The Company respectfully acknowledges the Staff's comment and advises the Staff that it has amended its disclosure on page v of the Registration Statement to include the requested information.

There is substantial doubt about our ability to continue as a "going concern," and we will require substantial additional funding..., page 6

5. Please update your risk factor disclosure to highlight how the Forbearance Agreement with Veru may impact your future capital requirements or otherwise advise.

The Company respectfully acknowledges the Staff's comment and advises the Staff that it has amended its disclosure on page 6 of the Registration Statement to include the requested information.

Our current liabilities are significant, and if those to whom we owe accounts payable, such as Veru, IQVIA or other creditors or vendors..., page 7

6. **We note your disclosure that you have accounts payable to IQVIA; however, we do not note disclosure elsewhere related to any agreement with IQVIA. Please revise your disclosure to clarify whether IQVIA is currently providing any material services to you or otherwise advise.**

The Company respectfully acknowledges the Staff's comment and advises the Staff that it has amended its disclosure on page 7 of the Registration Statement to include the requested information.

We owe a significant amount of money to Veru, which funds we do not have. Veru may take action..., page 7

7. **Please update your risk factor to disclose the material "certain forbearance terms."**

The Company respectfully acknowledges the Staff's comment and advises the Staff that it has amended its disclosure on page 7 of the Registration Statement to provide a reference to the requested information.

The life of patent protection is limited, and third parties could develop and commercialize methods, products, and technologies..., page 35

8. **We note your disclosure on page 36 that licensed patents and pending patent applications are "expected" to expire on various dates. We also not your disclosure on page 89 that one patent has already expired and another was set to expire on May 3, 2024. If material, please revise to disclose what effect you expect the expiration of these patents to have on your patent portfolio and your business and if you intend to take any action to mitigate such effect.**

The Company respectfully acknowledges the Staff's comment and advises the Staff that it has amended its disclosure on pages 35 and 89 of the Registration Statement to include the requested information.

ENTADFI, page 65

9. **We note your disclosure on page 66 that you agreed to pay Veru "15% of (i) the monthly cash receipts of Proteomedix for the licensing or sale of any products or services, (ii) monthly cash receipts of the Company or any of its subsidiaries for the sales of Proclarix anywhere in the world, and (iii) monthly cash receipts of the Company or any of its subsidiaries for milestone payments or royalties from Labcorp" as consideration for Veru's entrance into the Forbearance Agreement. Please revise your disclosure to clarify the term of the potential payments to Veru.**

The Company respectfully acknowledges the Staff's comment and advises the Staff that it has amended its disclosure on pages 65 and 105 of the Registration Statement to include the requested information.

About the Company
Products
Proclarix, page 69

10. **For each diagnostic test and decision support system described in this section, please revise to discuss in greater detail the technical development of each test including the remaining stages of technical development, regulatory filings or other requirements (i.e. the necessity of clinical studies, trials or other clearance or approvals) and associated costs and timelines. To the extent clinical studies or trials will be required, please discuss these requirements and any plans, costs and timelines to complete these studies or trials. Please include enough details so investors can clearly appreciate where each test resides in your development pipeline and the steps, costs and timelines necessary to obtain final regulatory approval.**

The Company respectfully acknowledges the Staff's comment and advises the Staff that it has amended its disclosure on pages 70-71 of the Registration Statement to include the requested information, and remove disclosure regarding programs that are not currently material.

11. **We note your disclosure elsewhere that you entered into an exclusive partnership with Labcorp in 2023 pursuant to which Labcorp has the exclusive right to develop and commercialize Proclarix in the United States. Please update your product pipeline figure and introductory disclosure to clarify this partnership.**

The Company respectfully acknowledges the Staff's comment and advises the Staff that it has amended its disclosure on page 68 of the Registration Statement to include the requested information.

12. **We note the inclusion of certain diagnostic candidates and decision support systems in your pipeline table, including Prediction (Rx), Prosgard Software and Prostate Cancer Decision Support. Given the limited disclosure related to these programs, please explain why they are sufficiently material to your business to warrant inclusion in your pipeline table. If they are material, please expand your disclosure in the Business section to provide a more fulsome discussion of these programs, including a description of development activities conducted. Alternatively, remove any programs that are not currently material from your pipeline table.**

The Company respectfully acknowledges the Staff's comment and advises the Staff that it has amended its disclosure on pages 68-71 of the Registration Statement to remove disclosure regarding programs that are not currently material.

13. We note your reference to a "Cockpit" in your pipeline table. Please clarify what this means or otherwise advise.

The Company respectfully acknowledges the Staff's comment and advises the Staff that it has amended its disclosure on page 68 of the Registration Statement to remove disclosure regarding this program, as it is not currently material.

14. **We note your pipeline table appears to depict Proclarix twice in the graphic, as a Decision Support System and a Diagnostic. However, your disclosure elsewhere appears to indicate that "Proclarix already consists of a decision support system integrating different values in a risk score" and appears to be one "Proclarix diagnostic program." Please revise your table or otherwise advise if the decision support system is separate from the diagnostic test.**

The Company respectfully acknowledges the Staff's comment and advises the Staff that it has amended its disclosure on page 68 of the Registration Statement to make clearer that Proclarix is a single diagnostic program.

Clinical Studies, page 70

15. **At first use, please provide a brief explanation of the disclosed p-value and how it is used to measure statistical significance.**

The Company respectfully acknowledges the Staff's comment and advises the Staff that it has amended its disclosure on pages 69-70 of the Registration Statement to include the requested information.

16. **With respect to the clinical studies, please clearly describe the primary endpoints, and whether these endpoints were met. To the extent that there were secondary endpoints, please clearly describe, and disclose whether such endpoints were met, or otherwise advise.**

The Company respectfully acknowledges the Staff's comment and advises the Staff that it has amended its disclosure on page 69-71 of the Registration Statement to include the requested information.

17. **Please provide the basis or data for the statement on page 71 that Proclarix was more accurate when compared to PSA density and online calculators, as well as the conclusion that Proclarix outperformed PSA density in the selection of candidates for prostate biopsy. You may provide an objective summary of the data that you used to draw such conclusions.**

The Company respectfully acknowledges the Staff's comment and advises the Staff that it has amended its disclosure on page 70 of the Registration Statement to include the requested information.

A novel serum biomarker quintet that improves disease prognosis in men with confirmed prostate cancer, page 72

18. **Please provide the basis or quantify your analysis showing that the proposed model had a better prediction for disease progression than the "CAPRA" score. In addition, please clarify, if true, that you conducted the clinical evaluation, or otherwise advise.**

The Company respectfully acknowledges the Staff's comment and advises the Staff that it has amended its disclosure on page 71 of the Registration Statement to include the requested information.

Market Opportunity
Proclarix, page 74

19. **We note your disclosure that the "worldwide market for in vitro diagnostic ("IVD") products was valued at $117.8 billion in 2022." However, we note that "Proclarix has been validated and approved for use in men with elevated total PSA (2.0 to 10.0 ng/mL), a normal DRE not suspicious for cancer and an elevated prostate volume (35 mL)." Please add balancing disclosure to clarify the addressable market for your specific product of product candidate.**

The Company respectfully acknowledges the Staff's comment and advises the Staff that it has amended its disclosure on page 73 of the Registration Statement to include the requested information.

Competition
Competitive Advantages of Proclarix, page 78

20. **With respect to referencing the insurance company as a "Payer," please disclose, if true, that this is a potential or desired stakeholder. In this regard, we note your disclosures on pages 60 and 73 that Proclarix is currently not reimbursed in Europe, and therefore patients pay for Proclarix out of pocket.**

The Company respectfully acknowledges the Staff's comment and advises the Staff that it has amended its disclosure on page 77 of the Registration Statement to include the requested information.

Intellectual Property, page 88

21. **We note your disclosure here that you partnered with New Horizon Health Limited and Immunovia AB. Please revise your disclosure to discuss the material terms of your partnerships. Please file these agreements as exhibits or advise. Refer to Item 601(b)(10)(ii)(A) of Regulation S-K.**

The Company respectfully acknowledges the Staff's comment and advises the Staff that it has amended its disclosure on page 88 of the Registration Statement to include the requested information, and filed these agreements as Exhibits 10.60, 10.61 and 10.62.

Patents, page 89

22. **Please revise your discussion of your intellectual property to clarify and disclose the specific material product, product groups and technologies to which such patents relate, whether they are owned or licensed, the type of patent protection you have, the expiration dates and the applicable material jurisdictions.**

The Company respectfully acknowledges the Staff's comment and advises the Staff that it has amended its disclosure on page 89-92 of the Registration Statement to include the requested information.

Certain Significant Relationships
Ology Agreement (which was later acquired by National Resilience, Inc.), page 104

23. We note your disclosure that you are "obligated to pay Ology an aggregate amount of approximately $2.8 million, plus reimbursement for materials and outsourced testing, which will be billed at cost plus 15%." Please revise your disclosure to (i) clarify the type of project or services Ology is performing under the agreement, (ii) disclose the aggregate potential payment remaining and (iii) disclose the term and termination provision of the project.

The Company respectfully acknowledges the Staff's comment and advises the Staff that it has amended its disclosure on page 106 of the Registration Statement to include the requested information.

Onconetix's Management's Discussion and Analysis of Financial Condition and Results of Operations
Overview, page 104

24. We note your response to comment 17 and re-issue in part. With respect to the license agreement with Laboratory Corporation of America Holdings, please revise to (i) disclose the aggregate amounts paid to date and the aggregate amount of remaining potential milestone payments; (ii) quantify the royalty payments on the net sales, or provide a range no greater than 10 percentage points; (iii) disclose when the royalty provisions expire; (iv) disclose the expiration date; and (v) describe any termination provisions.

The Company respectfully acknowledges the Staff's comment and advises the Staff that it has amended its disclosure on page 106 of the Registration Statement to include the requested information.

Services Agreement, page 105

25. Please identify the Vendor referenced in the Services Agreement.

The Company respectfully acknowledges the Staff's comment and advises the Staff that it has amended its disclosure on page 107 of the Registration Statement to include the requested information.

Selling Stockholders, page 153

26. We note your disclosure that the second column lists the number of shares of Common Stock beneficially owned by each Selling Stockholder, based on its ownership of the shares of Common Stock, PIOs, as of April 1, 2024. Please update this section to provide all required information in Item 507 of Regulation S-K, including the amount of securities held by the security holders prior to the offering, and the amount and (if one percent or more) percentage of the class to be owned by the security holders after completion of the offering.

The Company respectfully acknowledges the Staff's comment and advises the Staff that it has amended its disclosure on page 153 of the Registration Statement to include the requested information.

Onconetix, Inc.
Consolidated Balance Sheet, page F-4

27. Please revise to clearly identify any related party amounts on the face of your financial statements as required by Rule 4-08(k) of Regulation S-X. In this regard, we note that the PMX Investor, which is a party to your Subscription Agreement, is a 5% stockholder of the company.

The Company respectfully acknowledges the Staff's comment and advises the Staff that it has amended its disclosure throughout the financial statements to include the requested information.

ProteoMedix AG
Notes to Condensed Financial Statements
Note 3 - Summary of Significant Accounting Policies Revenue Recognition, page F-87

28. We note your tabular disclosure on page F-88 which disaggregates ProteoMedix revenues by type for the periods ended September 30, 2023 and 2022. Please revise to clarify whether product sales are derived from sales of Proclarix in the European Union. If not, please clarify from where such product sales are derived. Please also revise to provide the customer concentration disclosures required by ASC 275-10-50-18. In this regard, we note your disclosure on page 122 that development services revenue was attributable to a contract with a single customer while license revenue was attributable to a one-time licensing contract. Please also revise your revenue throughout your document accordingly.

The Company respectfully acknowledges the Staff's comment and advises the Staff that it has amended its disclosure on pages F-10 and F-119 of the Registration Statement to include the requested information.

General

29. At first use, please define abbreviations throughout your registration statement. For example only, we note "BPH" on page 1, "DRE" on page 70, which do not appear to be defined.

The Company respectfully acknowledges the Staff's comment and advises the Staff that it has amended its disclosure throughout the Registration Statement to define abbreviations.

30. Many of your tables and graphics include print that is not legible. For example only, your Figure 4 and 5 contains text that is too small to be legible. Please revise your graphics throughout your prospectus as applicable to ensure that the text is legible.

The Company respectfully acknowledges the Staff's comment and advises the Staff that it has revised the graphics throughout the Registration Statement to ensure that the text is legible.

31. We note your disclosure throughout your registration statement that Proclarix is "expected to be available in the United States ("*U.S.*") in the near future." We also note, pursuant to your license agreement with Labcorp, "Labcorp is wholly responsible for the cost, if any, of research, development and commercialization of Licensed Products in the United States." Please revise your disclosure to clarify the current regulatory status of Proclarix in the United States or otherwise advise.

The Company respectfully acknowledges the Staff's comment and advises the Staff that it has amended its disclosure on page 98 of the Registration Statement to include the requested information.

* * *

We thank the Staff for its review of this response. Should you have any questions or require any additional information, please do not hesitate to contact our legal counsel, Jessica Yuan, Esq. of Ellenoff Grossman & Schole LLP, at jyuan@egsllp.com or by telephone at (212) 370-1300.

Very truly yours,

Onconetix, Inc.

By: */s/ Bruce Harmon*
Name: Bruce Harmon
Title: Chief Financial Officer

cc: Ellenoff Grossman & Schole LLP