

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

VIA EDGAR

April 26, 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.
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 March 12, 2024, relating 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. 1 to the Registration Statement (the “**Amended Registration Statement**”), which is being submitted to the Commission contemporaneously with the submission of this letter.

Registration Statement on Form S-1

Prospectus Summary, page 1

- 1. We note your disclosure that local diagnostic laboratories can easily add Proclarix, an affordable multiparametric test, to their existing infrastructure. Please provide balancing disclosure with your statement on page 17 that Proclarix is complicated and expensive to manufacture or otherwise advise.**

Response: The Company respectfully acknowledges the Staff’s comment and advises the Staff that it has amended its disclosure on pages 2-3 of the Registration Statement to include the requested information.

2. **We note your disclosure that “ENTADFI will become the inaugural therapeutic drug in [your] expanding portfolio of oncology therapeutics once launched.” However, we note that ENTADFI appears to be approved for an indication outside of the field of oncology and you do not describe any other oncology therapeutics approved or under development. Please update your disclosure to describe your “expanding portfolio of oncology therapeutics” or otherwise revise.**

Response: The Company respectfully acknowledges the Staff’s comment and advises the Staff that it has amended its disclosure on page 1 of the Registration Statement.

Overview of Company, page 5

3. **We note your disclosure that “In Europe, Proteomedix has begun marketing Proclarix to pilot laboratories in selected markets that are open to self-pay to show initial adoption.” Please expand your disclosure to clarify and describe the material details of the marketing of Proclarix to date. For example only, please revise your disclosure to describe when you launched Proclarix and quantify how it has been accepted to date. In addition, please clarify what “self-pay” means.**

Response: The Company respectfully acknowledges the Staff’s comment and advises the Staff that it has amended its disclosure on pages 59-60 of the Registration Statement to include the requested information and to clarify what “self-pay” means.

4. **We note your disclosure that “Proclarix is approved for sale in the European Union under the IVDR.” Please revise your disclosure to clarify when the diagnostic was approved and describe the specific target market for Proclarix or otherwise advise.**

Response: The Company respectfully acknowledges the Staff’s comment and advises the Staff that it has amended its disclosure on page 59 of the Registration Statement to include the requested information.

Recent Acquisitions
Proteomedix, page 5

5. **We note that you acquired Proteomedix AG on December 15, 2023 in a share exchange transaction whereby the aggregate value of your exchange shares at closing was equal to approximately \$75 million less the value of the Proteomedix Shares. Please revise your filing to include Proteomedix’s audited and unaudited financial statements and related pro forma financial statements pursuant to Rule 8-04 and Rule 8-05 of Regulation S-X similar to those included within your amended Form 8-K filed on February 27, 2024.**

Response: The Company respectfully acknowledges the Staff’s comment and advises the Staff that it has included Proteomedix’s audited and unaudited financial statements and related pro forma financial statements in the Amended Registration Statement on pages 97-101.

6. **The pro forma financial information included as Exhibit 99.3 to your amended Form 8-K filed on February 27, 2024 indicates that Onconetix was determined to be the accounting acquirer in the share exchange agreement with Proteomedix. Please provide to us your detailed analysis of the guidance at ASC 805-10-55-10 through 15 for this transaction to explain how you determined that Onconetix is the accounting acquirer under U.S. GAAP. Please also revise to provide expanded disclosures as to how you determined Onconetix is the acquiring entity. In this regard, we note that upon consummation of this transaction, as well as the related Conversion and Subscription transactions, Proteomedix shareholders were to own 87.2% of the combined company.**

Response: The Company respectfully acknowledges the Staff’s comment and advises the Staff that it has amended its disclosure of page F-28 of the Registration Statement to include the requested information.

7. **We note that you issued 3,675,414 shares of common stock and 2,696,729 shares of series B convertible preferred stock and that you determined that the purchase price was \$62.5 million. Please revise your filing to explain how you determined that the fair value of the shares exchanged in this transaction were \$62.5 million. In this regard, you indicate that the 3,675,414 shares of common stock issued were valued at \$1.1 million based on a per share price of \$0.30. Please explain how this per share price was determined in relation to your quoted market price. Please also explain how you determined that the 2,696,729 shares of series B convertible preferred stock issued were valued at \$61.3 million.**

Response: The Company respectfully acknowledges the Staff's comment and advises the Staff that it has amended its disclosure of page 60 of the Registration Statement to include the requested information.

8. **We note that you allocated \$51.1 million of the purchase price to internally-developed technology with a useful life of 15 years. Please tell us and revise your filing to explain the nature of this technology, how you determined the fair value of this technology and determined its useful life.**

Response: The Company respectfully acknowledges the Staff's comment and advises the Staff that it has amended its disclosure of page 101 of the Registration Statement to include the requested information.

9. **Please identify the "Investor" referenced in this section.**

Response: The Company respectfully acknowledges the Staff's comment and advises the Staff that it has amended its disclosure on page 59 of the Registration Statement to include the requested information.

10. **It appears that you are attempting to rely on Instruction VII to Form S-1 to incorporate by reference previously filed and future filings of Exchange Act reports. Because you have not yet filed your Form 10-K for your most recently completed fiscal year, December 31, 2023, it appears that you have not satisfied the requirements of paragraph C of that instruction. Please revise your filing to include all disclosures required by Form S-1.**

Response: The Company respectfully acknowledges the Staff's comment and advises the Staff that the Company filed its Annual Report on Form 10-K for its most recently completed fiscal year ended December 31, 2023 on April 11, 2024, and as such, the Company believes that the Amended Registration Statement satisfies paragraph C of Instruction VII to Form S-1.

ENTADFI, page 9

11. **We note your disclosure that "[p]ursuant to the Amendment, [you] agreed to use commercially reasonable efforts to obtain such shareholder approval by December 31, 2023." Please revise your disclosure to clarify whether or not you received shareholder approval for the issuance of shares of Common Stock upon conversion of your Series A Preferred Stock or otherwise advise. In addition, if applicable, describe any ramifications if such shareholder approval is not obtained or otherwise advise.**

Response: The Company respectfully acknowledges the Staff's comment and advises the Staff that it has amended its disclosure on page 66 of the Registration Statement to include the requested information.

12. **We note you "purchased substantially all of the assets related to Veru ENTADFI business and assumed certain liabilities of Veru." Please revise your disclosure to describe the "certain liabilities" you assumed.**

Response: The Company respectfully acknowledges the Staff's comment and advises the Staff that it has amended its disclosure on page 65 to remove the reference to "certain liabilities".

13. **We note your transaction with Veru for ENTADFI closed in April 2023. Please update your disclosure here to clarify that you have not generated any revenue from product sales of ENTADFI consistent with your disclosure elsewhere. In addition, please update your disclosure to clarify and quantify where you are at in “building out [y]our commercial capabilities to launch ENTADFI” or otherwise advise.**

Response: The Company respectfully acknowledges the Staff’s comment and advises the Staff that it has amended its disclosure on pages 2, 57 and 102 of the Registration Statement to include the requested information.

Risk Factors

There is substantial doubt about our ability to continue as a “going concern.”, page 14

14. **We note your disclosure that you do not currently have sufficient cash to redeem the shares of Series B Convertible Preferred Stock. Please quantify the amount of cash required to redeem the shares of Series B Convertible Preferred Stock as of a recent date.**

Response: 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.

We may have violated, as amended (the “Exchange Act”) implementing Section 402 of the Sarbanes-Oxley Act of 2002)...., page 15

15. **Please specify the “certain expenses” you paid to your former CEO and Chairman, and disclose the material terms of such loans.**

Response: The Company respectfully acknowledges the Staff’s comment and advises the Staff that it has amended its disclosure on page 44 of the Registration Statement to include the requested information.

General

16. **We note your acquisitions of substantially all of the assets related to Veru ENTADFI on April 19, 2023 and your acquisition of Proteomedix on December 15, 2023, as well as your disclosures that you are currently focusing your efforts on building out your commercial capabilities to launch ENTADFI in the marketplace and commercializing Proclarix. Please provide a description of your business that addresses the requirements of Item 101 of Regulation S-K.**

Response: The Company respectfully acknowledges the Staff’s comment and advises the Staff that it has amended its disclosure in the section titled “*About the Company*” beginning on page 56 of the Registration Statement to include additional disclosure required by Item 101 of Regulation S-K.

17. **We note the reference on page 6 to your exclusive license agreement with Laboratory Corporation of America Holdings. Please describe the material terms of the agreement and file the agreement as an exhibit to the registration statement or tell us why you believe it is not a material contract. Refer to Item 601(b)(10) of Regulation S-K.**

Response: The Company respectfully acknowledges the Staff’s comment and advises the Staff that it has amended its disclosure on page 104 of the Registration Statement to include the requested information and has filed the exclusive license agreement with Laboratory Corporation of American Holdings as Exhibit 10.55 to the Amended Registration Statement.

18. **Please file the employment agreement with Ralph Schiess and the severance agreements with Jon Garfield and Dr. Neil Campbell as exhibits to your registration statement or otherwise advise. Refer to Item 601(b)(10) of Regulation S-K.**

Response: The Company respectfully acknowledges the Staff’s comment and advises the Staff that it has filed the employment agreements with Ralph Schiess and the severance agreements with Jon Garfield and Dr. Neil Campbell as Exhibits 10.21 through 10.28 to the Amended Registration Statement.

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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@egslp.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