



DIVISION OF  
CORPORATION FINANCE

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

March 12, 2024

Ralph Schiess  
Interim Chief Executive Officer  
Onconetix, Inc.  
201 E. Fifth Street, Suite 1900  
Cincinnati, OH 45202

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

Dear Ralph Schiess:

We have reviewed your registration statement and have the following comments.

Please respond to this letter by amending your registration statement and providing the requested information. If you do not believe a comment applies to your facts and circumstances or do not believe an amendment is appropriate, please tell us why in your response.

After reviewing any amendment to your registration statement and the information you provide in response to this letter, we may have additional comments.

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.
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.

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.
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.

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.
6. The pro forma financial information included as Exhibit 99.3 to your amended Form 8-K filed on February 27, 2024 indicates that 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.
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.

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

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.
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.
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.

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.

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.

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.
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 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.
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.

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.

Refer to Rules 460 and 461 regarding requests for acceleration. Please allow adequate time for us to review any amendment prior to the requested effective date of the registration statement.

Please contact Tara Harkins at 202-551-3639 or Angela Connell at 202-551-3426 if you have questions regarding comments on the financial statements and related matters. Please contact Jimmy McNamara at 202-551-7349 or Jason Drory at 202-551-8342 with any other questions.

Sincerely,

Division of Corporation Finance  
Office of Life Sciences

cc: Jessica Yuan