United States securities and exchange commission logo

May 10, 2024

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

Re: Onconetix, Inc.
Amendment No. 1 to Registration Statement on Form S-1
Filed April 26, 2024
File No. 333-277066

Dear Ralph Schiess:

We have reviewed your amended 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. Unless we note otherwise, any references to prior comments are to comments in our March 12, 2024 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."
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.

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.

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.

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.

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.

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 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.

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.

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.

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.

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.

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

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.

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.

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.

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.

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.
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.
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.
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.

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.
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.
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.
Services Agreement, page 105

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

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.
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.
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.
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.

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.

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