

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

FORM 8-K

CURRENT REPORT

Pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934

Date of Report (Date of earliest event reported): December 19, 2023

Onconetix, Inc.

(Exact name of registrant as specified in its charter)

Delaware

(State or other Jurisdiction
of Incorporation)

001-41294

(Commission File Number)

83-2262816

(IRS Employer
Identification No.)

201 E. Fifth Street, Suite 1900 Cincinnati, Ohio

(Address of Principal Executive Offices)

45202

(Zip Code)

Registrant's telephone number, including area code: **(513) 620-4101**

(Former name or former address, if changed since last report.)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

- Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
- Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
- Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
- Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Securities registered pursuant to Section 12(b) of the Act:

Title of Each Class	Trading Symbol(s)	Name of Each Exchange on Which Registered
Common Stock, par value \$0.00001 per share	BWV	The Nasdaq Stock Market LLC

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

Emerging growth company

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act.

Item 7.01 Regulation FD Disclosure.

On December 19, 2023, Onconetix, Inc., a Delaware corporation (the “Company”) issued a press release announcing the issuance of a letter to shareholders from the Company’s Chief Executive Officer, Dr. Neil Campbell (the “Press Release”). The Press Release is attached hereto as [Exhibit 99.1](#) and is being furnished herewith.

The information in this Item 7.01 of this Current Report on Form 8-K (the “Current Report”) and the Press Release being furnished herewith shall not be deemed “filed” for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, or otherwise subject to the liabilities of that section or Sections 11 and 12(a)(2) of the Securities Act of 1933, as amended. The information contained in this Item 7.01 and in the Press Release attached as [Exhibit 99.1](#) to this Current Report shall not be incorporated by reference into any filing with the Securities and Exchange Commission made by the Company, whether made before or after the date hereof, regardless of any general incorporation language in such filing.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits

99.1*	Press Release, dated December 19, 2023
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)

* Furnished herewith

SIGNATURE

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

Date: December 19, 2023

Onconetix, Inc

By: /s/ Dr. Neil Campbell

Dr. Neil Campbell
Chief Executive Officer

Onconetix Chief Executive Officer Dr. Neil J. Campbell Issues Letter to Shareholders

CINCINNATI, December 19, 2023 – Onconetix, Inc., (Nasdaq: BWV) (“Onconetix” or the “Company”) today issued the following shareholder letter from the Company’s Chief Executive Officer, Dr. Neil Campbell.

To Our Valued Shareholders,

As 2023 draws to a close, I am eager to share with you the significant strides Onconetix, Inc. (formerly Blue Water Biotech, Inc.) has made in our journey towards becoming a leader in oncology. This past quarter has been transformative, marked by strategic shifts and notable achievements, all aimed at enhancing the value we bring to you as our shareholders.

To reflect our recent achievements and renewed oncology focus, we have rebranded as Onconetix™, Inc. This rebranding reflects a transformation of the business to one focused on the research, development and commercialization of proprietary science and technologies for therapeutics, diagnostics, and services for the treatment of cancer.

A key component of our focus is Entadfi®, an FDA-approved, once-daily oral treatment for benign prostatic hyperplasia (BPH). Set for launch in 2024, Entadfi® is poised to be an important product in our oncology therapeutics portfolio and has the potential to be a first-line treatment for BPH symptoms.

However, our larger strategy and vision for our commercial portfolio is a dual therapeutic and diagnostic approach. With our recent acquisition of Proteomedix, a commercial stage European oncology diagnostics company headquartered in Zurich, Switzerland, we have achieved just that. Now our cornerstone products are Entadfi® for the treatment of benign prostatic hyperplasia and Proclarix® for prostate cancer diagnostics.

In addition to significantly enhancing our emerging commercial portfolio, the acquisition of Proteomedix and its diagnostic platform marks a milestone in expanding our diagnostic capabilities worldwide. Proclarix® is CE-certified and adhering to both European (EAU) and American (AUA) guidelines. Proclarix® is already available in Europe and will be introduced in the U.S. through an exclusive partnership with a U.S. major laboratory corporation.

Joining the senior management team of Onconetix will be Dr. Ralph Schiess, PhD, co-founder of Proteomedix, as Chief Science Officer, and Mr. Christian Brühlmann, co-founder of Proteomedix, as Chief Strategy Officer and General Manager of Europe.

Finally, in line with our commitment to oncology, we have transitioned away from our preclinical vaccine programs. These programs are now transitioning back to our vaccine partners, ensuring their continued progress by others while we direct our resources towards more targeted initiatives in oncology.

As you can see, our strategy, bolstered by our latest acquisition, lays a solid foundation for Onconetix™ in the oncology sphere. We are focused on cultivating key partnerships, acquiring vital assets, and initiating our commercial revenue phase. Our goal is to build a company that is not only focused on growth for shareholders, but also on providing innovative solutions to clinicians, patients, and caregivers.

Your continued support and trust in Onconetix™ are invaluable to us. We are excited about the future and are committed to delivering on our promise of bringing groundbreaking solutions to the field of oncology.

Thank you for being a part of our journey.

Sincerely,

Dr. Neil J. Campbell
President & CEO
Onconetix, Inc.

About Onconetix, Inc.

Onconetix, Inc. (formerly Blue Water Biotech Inc. (BWV)) is a commercial stage biotechnology company focused on the research, development and commercialization of proprietary therapeutics, diagnostics and services for clinicians and patients for oncology. The Company currently has Entadfi[®], an FDA approved, oral therapeutic for the treatment of benign prostatic hyperplasia (BPH), a disorder of the prostate, and Proclarix[®], an advanced proprietary diagnostic system for screening and diagnosis for men with indeterminate Prostate Specific Antigen (PSA) assessments in prostate cancer oncology. For more information, visit www.onconetix.com.

Forward-Looking Statements

Certain statements in this press release are forward-looking within the meaning of the Private Securities Litigation Reform Act of 1995. These statements may be identified by the use of forward-looking words such as “anticipate,” “believe,” “forecast,” “estimate,” “expect,” and “intend,” among others. These forward-looking statements are based on Blue Water’s current expectations and actual results could differ materially. There are a number of factors that could cause actual events to differ materially from those indicated by such forward-looking statements. These factors include, but are not limited to, risks related to Blue Water’s ability to integrate the Transaction described herein; risks related to Blue Water’s ability to commercialize ENTADFI[®] and Proclarix[®] described herein; risks related to Blue Water’s ability to expand its business scope and integrate the assets and commercial operations acquired in the Transaction into Blue Water’s business; risks related to Blue Water’s ability to attract, hire and retain skilled personnel necessary to commercialize and operate the company’s commercial products; the failure to obtain FDA clearances or approvals and noncompliance with FDA regulations; risks related to the timing and progress of clinical development of our product candidates in oncology; our need for additional financing; uncertainties of patent protection and litigation; uncertainties of government or third party payor reimbursement; limited research and development efforts and dependence upon third parties; and substantial competition. Blue Water does not undertake an obligation to update or revise any forward-looking statement. Investors should read the risk factors set forth in Blue Water’s Annual Report on Form 10-K, filed with the Securities and Exchange Commission (the “SEC”) on March 9, 2023, and periodic reports filed with the SEC on or after the date thereof. All of Blue Water’s forward-looking statements are expressly qualified by all such risk factors and other cautionary statements. The information set forth herein speaks only as of the date thereof.

Investor and Media Contact Information:

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