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 18, 2023

Onconetix, Inc.
(Exact name of registrant as specified in its charter)

Delaware	**001-41294**	**83-2262816**
(State or other Jurisdiction of Incorporation)	(Commission File Number)	(IRS Employer Identification No.)

201 E. Fifth Street, Suite 1900 Cincinnati, Ohio	**45202**
(Address of Principal Executive Offices)	(Zip Code)

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

Blue Water Biotech, Inc.
(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 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 8.01 Other Events.

On December 18, 2023, Blue Water Biotech, Inc. (the "Company"), issued a press release announcing the acquisition of Proteomedix AG, a private, commercial-stage diagnostics oncology company, and introducing Onconetix, Inc. as the new name of the combined company (the "Press Release"). The Press Release is attached hereto as Exhibit 99.1 and incorporated herein by reference.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits

99.1	Press Release, dated December 18, 2023.
104	Cover Page Interactive Data File (embedded within the Inline XBRL document).

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.

Onconetix, Inc.

Date: December 18, 2023

By: /s/ Dr. Neil Campbell
Dr. Neil Campbell
Chief Executive Officer

Exhibit 99.1

Blue Water Biotech Acquires Proteomedix as Part of Transformation to Commercial Stage Oncology Company; Announces Name Change to Onconetix™

Transaction strengthens commercial business with addition of diagnostics product and initial focus on prostate cancer

CINCINNATI, Dec. 18, 2023 (GLOBE NEWSWIRE) -- Blue Water Biotech Inc. (Nasdaq: BWV) ("BWB" or the "Company") today announced the acquisition of Proteomedix AG, a private, commercial-stage diagnostics oncology company (the "Transaction"), and introduced a new name for the combined Company: Onconetix Inc. The Transaction 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.

The acquisition of Proteomedix for all stock consideration provides its shareholders with an initial 19.9% ownership stake of Onconetix.

With the transaction Onconetix establishes a European headquarter with operations in Zurich, Switzerland. Two members of Proteomedix' leadership team will become executives of Onconetix™.

Onconetix™' commercial products are Entadfi®, an FDA-approved, once-daily oral therapeutic for the treatment of benign prostatic hyperplasia (BPH), and Proclarix®, a European CE IVD approval for prostate diagnostics and a lab developed test (LDT) currently in the U.S., originally developed by Proteomedix.

The new focus of Onconetix™ aligns the business with the market value drivers in oncology and extensive life sciences company-building expertise of its new leadership team under the direction of President and CEO, Dr. Neil J. Campbell.

"As physicians and patients face a myriad of medical challenges, particularly in the area of benign prostatic hyperplasia (BPH) and prostate cancer, Onconetix is committed to innovation and bringing global leadership to this area of need," said Dr. Campbell. "This pivotal move not only expands our global footprint, it enables us to harness the advanced technological platform and diagnostic expertise of Proteomedix. Furthermore, it is an important step in our overall transformation as a Company that strengthens our core mission of enhancing shareholder value and positions us at the emerging forefront of prostate cancer diagnostics," said Dr. Campbell.

Tungsten Advisors served as the exclusive financial advisor to Proteomedix AG.

About ENTADFI®

ENTADFI® is a once-daily, oral treatment for BPH that combines finasteride, a 5α-reductase inhibitor, and tadalafil, a phosphodiesterase 5 (PDE5) inhibitor, offering a more effective treatment option compared to other available therapies. We believe that ENTADFI® will potentially improve the compliance issues in taking currently available therapies due to side effects associated with available therapies. Clinical trials have shown that ENTADFI® is more effective in treating BPH symptoms, including urinary frequency, urgency, weak stream and difficulty initiating or maintaining urination, compared to finasteride monotherapy. Additionally, ENTADFI® has demonstrated a favorable safety profile, with fewer adverse sexual side effects compared to finasteride. ENTADFI® reduces potential for adverse sexual side effects, making it a preferred choice for men seeking relief from BPH symptoms without compromising their sexual health. ENTADFI® has received FDA approval for the indication of initiating treatment of the signs and symptoms of BPH in men with an enlarged prostate for up to 26 weeks. More information about BPH and full ENTADFI® prescribing information can be found on the product website at https://entadfipatient.com/.

About Proclarix®

Proclarix® is CE-certified under IVDR in Europe and indicated for prostate cancer diagnosis in patients with normal digital rectal exam (DRE), enlarged prostate volume and elevated levels of PSA at 2-10 ng/ml. Proclarix ®is a risk score combining in-vitro assays for the quantitative detection of biomarkers with a proprietary algorithm to assess a patient's risk of having clinically significant prostate cancer. Detection of prostate cancer-related biomarkers in blood serum using the Proclarix® risk score has been demonstrated in multiple clinical studies to be a reliable indicator of the presence of clinically significant prostate cancer. Proclarix® is available in Europe and expected to launch in the U.S. in 2024.

About Proteomedix AG

Proteomedix is a healthcare company whose mission is to transform prostate cancer diagnosis. The company has identified novel biomarker signatures with utility in prostate cancer diagnosis, prognosis and therapy management. The lead product Proclarix® is a blood-based prostate cancer test panel and risk score currently available in Europe and expected to be available in the U.S. in 2024. Proteomedix is located in the Bio-Technopark of Zurich-Schlieren, Switzerland. For more information, visit www.proteomedix.com.

About Onconetix, Inc.

Onconetix Inc. (Nasdaq: ONCO) (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.

About Tungsten Advisors

Tungsten Advisors (www.tungstenadv.com) is an investment banking firm focused on strategic advisory and corporate finance for healthcare and technology companies. Tungsten provides transactional services including financings (private placements/PIPEs), corporate licensing and mergers and acquisitions (M&A). Tungsten also focuses on company incubation and makes direct investments alongside the creation of new companies in healthcare and technology.

Securities offered through Finalis Securities LLC Member FINRA/SIPC. Tungsten Partners LLC d/b/a Tungsten Advisors and Finalis Securities LLC are separate, unaffiliated entities.

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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.