

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): October 30, 2023

Blue Water Biotech, 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 October 30, 2023, Blue Water Biotech, Inc., a Delaware corporation (the “Company”), issued a press release announcing the issuance of a letter to shareholders from its 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 October 30, 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.

Blue Water Biotech, Inc.

Date: October 30, 2023

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

Blue Water Biotech Issues Letter to Shareholders

Blue Water Biotech Issues Letter to Shareholders

October 30, 2023 at 7:00 AM EDT

CINCINNATI, Oct. 30, 2023 (GLOBE NEWSWIRE) -- Blue Water Biotech, Inc. (Nasdaq: BWV) (“BWB” or the “Company”) today issued the following shareholder letter from the Company’s Chief Executive Officer Dr. Neil Campbell.

Dear Shareholders,

As we close out October and the first month under my tenure, I want to take this opportunity to personally communicate with you while providing an update on the direction of Blue Water Biotech.

2023 has been an eventful year that has significantly influenced the Company’s progression in generating shareholder value. On October 24, 2023, Blue Water Biotech received a letter from Nasdaq informing the Company that it is back in compliance with the Nasdaq Stock Market, LLC Listing Rule 5250(c)(1). This completes our outstanding obligations to the Nasdaq, and we will work diligently moving forward on this corporate requirement.

As a result of our internal assessments, the Company made a strategic decision to establish a new management team equipped with the necessary capabilities to swiftly advance our operations in the field of oncology.

As part of the shift in business strategy and to enhance shareholder value, the Company will focus its efforts on building a foundation of therapeutic, diagnostic, and service products in the field of oncology that will bolster and enrich the practice of medicine for clinicians.

With that in mind, a pivotal milestone for us is the impending launch of Entadfi[®], an FDA-approved oral drug designed to treat benign prostatic hyperplasia (BPH). With the 2024 launch of Entadfi[®] it will become the inaugural therapeutic drug in our expanding portfolio of oncology therapeutics.

So where does this leave us with initiatives outside of our new focus? The Company’s previous activities in acquiring assets from WraSer, and Xspire Pharma, in early 2023 have been reassessed for strategic and tactical market considerations. It has been decided that these assets would not meet the Company’s requirements for creating greater shareholder value as we move into 2024.

Additionally, as a component of the asset purchase agreement involving WraSer and Xspire Pharma, the Company established commercial relationships intended for the marketing and sale of drug assets that are not aligned with our new oncology focus. Consequently, we have ceased this operation, recognizing its misalignment with our Company’s evolving objective in the field of oncology.

Finally, the Company has established early stage preclinical and clinical programs in various vaccine technologies. These vaccine programs were targeting a wide number of diseases and conditions that would have consumed an enormous amount of Company resources. Considering the evolving market dynamics and post-pandemic challenges, we conducted a strategic and tactical assessment, leading us to conclude that the optimal path for the Company lies in a de-prioritization of the vaccine programs to focus our efforts on the expansion of our oncology offerings.

In summary, our business strategy shift aims to enhance shareholder value by establishing a strong foothold in both therapeutic and diagnostic aspects within the field of oncology. This approach involves actively cultivating key relationships and acquiring essential assets to lay the foundation in oncology and launch our initial stages of commercial revenue. With this, we eagerly anticipate building an accretive and focused company, providing leading-edge therapeutics, diagnostics, and services to clinicians, patients, and caregivers.

Thank you for your continued support of Blue Water Biotech.

Sincerely,

Dr. Neil Campbell
President & CEO
Blue Water Biotech, Inc.

About Blue Water Biotech, Inc.

Blue Water Biotech, Inc. is a commercial stage biotechnology company focused on the research, development, and commercialization of innovative solutions for oncology. The Company currently has Entadfi[®], an oral therapeutic for the treatment of benign prostatic hyperplasia (BPH), a disorder of the prostate, along with building additional assets in therapeutics, diagnostics, and clinician services for oncology.

Investor and Media Contact Information:

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