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): April 25, 2023

Blue Water Biotech, 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**

(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 April 25, 2023, Blue Water Biotech, Inc., a Delaware corporation (the "Company") issued a press release announcing that Company management will attend the American Urological Association Annual Meeting (the "AUA Annual Meeting") in Chicago, Illinois from April 28, 2023 to May 1, 2023, to promote its asset ENTADFI®, an FDA-approved treatment for benign prostatic hyperplasia (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 SEC 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 April 25, 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: April 25, 2023

By: /s/ Joseph Hernandez

Joseph Hernandez
Chief Executive Officer

Exhibit 99.1

Blue Water Biotech to Participate in the American Urological Association Annual Meeting 2023 to Promote Benign Prostatic Hyperplasia Treatment ENTADFI®

CINCINNATI, OH, April 25, 2023 -- Blue Water Biotech, Inc. ("Blue Water" or the "Company"), a biotechnology company spanning multiple sectors, today announced that Blue Water management will attend the American Urological Association ("AUA") Annual Meeting 2023 in Chicago, IL from April 28th to May 1st, 2023, to promote its asset ENTADFI®, an FDA-approved treatment for benign prostatic hyperplasia ("BPH").

Blue Water's Chief Executive Officer, Joseph Hernandez, and Senior Vice President of Marketing and Business Development, Frank Jaeger, will be in attendance to discuss launch strategy for ENTADFI® scheduled for later this year, as well as the benefits of ENTADFI® versus traditional BPH therapies. Hernandez and Jaeger will also be available to discuss the recent rebranding of Blue Water, its transition into a commercial-stage biotechnology company, and the infrastructure being developed to support sales of ENTADFI®.

"This conference brings together the top urology leaders from around the country, and we are thrilled to attend to promote ENTADFI®," said Hernandez. "We believe this product has the potential to transform the BPH landscape and enhance the lives of millions of men that suffer from BPH and associated erectile dysfunction. We encourage all in attendance to visit our booth to connect and learn about ENTADFI®, as we prepare for launch later this year."

BPH, a condition in men in which the prostate gland is enlarged but not cancerous, is a common problem that affects the quality of life in approximately half of men over the age of 50 and over 90% of men over the age of 85. Men with BPH suffer from challenges with urination flow, frequency, and urgency, and about 70% of men with BPH also experience sexual dysfunction. In 2022, there were approximately 44 million total prescriptions and 20 million new prescriptions related to BPH symptoms. ENTADFI® is designed to treat BPH and its associated symptoms. Over 55 million patients in the United States have or are at risk for BPH.

Blue Water management will be available during the conference for one-on-one meetings and can be found at booth 439. Interested parties may request a one-on-one meeting at investors@bluewatervaccines.com or contact Blue Water at (513) 620-4101.

About ENTADFI®

ENTADFI® is an oral, once daily treatment for benign prostatic hyperplasia ("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. 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 Blue Water Biotech

Blue Water Biotech, Inc. is a biotechnology company focused on developing transformational therapies to address significant health challenges globally. Headquartered in Cincinnati, OH, the Company holds the rights to proprietary technology developed at the University of Oxford, Cincinnati Children's Hospital Medical Center, St. Jude Children's Hospital, and The University of Texas Health Science Center at San Antonio. Blue Water is developing a Streptococcus pneumoniae vaccine candidate, designed to specifically prevent highly infectious middle ear infections, known as acute otitis media (AOM), in children, and prevention of pneumonia in the elderly. The Company is also developing a universal flu vaccine that will provide protection from all virulent strains in addition to licensing a novel norovirus (NoV) S&P nanoparticle versatile virus-like particle (VLP) vaccine platform from Cincinnati Children's to develop vaccines for multiple infectious diseases, including Marburg and monkeypox, among others. Additionally, the Company is developing a Chlamydia vaccine candidate with UT Health Science Center San Antonio to prevent infection and reduce the need for antibiotic treatment associated with contracting Chlamydia disease. Outside of its vaccine franchise, Blue Water owns ENTADFI®, an FDA-approved, once daily pill that combines finasteride and tadalafil for the treatment of benign prostatic hyperplasia. This combination allows men to receive treatment for their symptoms of BPH without the negative sexual side effects typically seen in patients on finasteride alone. For more information about Blue Water, visit www.bluewatervaccines.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 realize the benefits of its acquisition of ENTADFI®, risks related to BWV's ability to expand its business scope and its ability to commercialize ENTADFI®, risks related to the development of Blue Water's vaccine candidates; the failure to obtain FDA clearances or approvals and noncompliance with FDA regulations; delays and uncertainties caused by the global COVID-19 pandemic; risks related to the timing and progress of clinical development of our product candidates; 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. As with any vaccine under development, there are significant risks in the development, regulatory approval and commercialization of new products. 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.

Media Contact Information:
Blue Water Media Relations
Telephone: (646) 942-5591
Email: Nic.Johnson@russopartnersllc.com

Investor Contact Information:
Blue Water Investor Relations
Email: investors@bluewatervaccines.com