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): July 17, 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 July 17, 2023, Blue Water Biotech, Inc., a Delaware corporation (the "Company"), issued a press release announcing the issuance of a letter to shareholders from its Chairman and Chief Executive Officer, Joseph Hernandez (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 July 17, 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: July 17, 2023

By: /s/ Joseph Hernandez

Joseph Hernandez
Chief Executive Officer

Exhibit 99.1

Blue Water Biotech Issues CEO Shareholder Letter Providing Update on Commercial Launch Activities

CINCINNATI, OH, July 17, 2023 - Blue Water Biotech, Inc. ("Blue Water" or the "Company") (Nasdaq: BWV), a biotechnology and pharmaceutical company focused on developing and commercializing transformational therapies to address significant health challenges globally, today issued the following letter to shareholders from its Chairman and Chief Executive Officer, Joseph Hernandez.

Dear Fellow Shareholders,

In recent months, Blue Water Biotech, Inc. ("Blue Water") has evolved from a preclinical vaccine development company to a commercial stage pharmaceutical company after the purchase of several FDA approved assets spanning multiple treatment areas. Capital raises in 2022, resulting in a strong cash position at the beginning of 2023, enabled us to pursue these strategic acquisitions. We believe the acquisition of these assets will generate tremendous value for Blue Water, and we are pleased to provide an update on our commercial launch progress thus far and milestones we intend to achieve in the coming months.

Our recent acquisitions include ENTADFI®, an FDA approved, once daily pill combining finasteride and tadalafil for the treatment of benign prostatic hyperplasia ("BPH"), and six additional FDA approved assets across multiple indications, including cardiology, inner and outer ear infections, and pain management. While each product has unique considerations for launch and we have analyzed each closely, we have developed a core framework for commercial operations as we progress towards official launch.

To begin, the core for any successful commercial operation is a dedicated, experienced management team to steer operations and make strategic decisions that will benefit Blue Water in the long run. In February 2023, we appointed Frank Jaeger to the team as Senior Vice President of Marketing and Business Development, bringing with him over 25 years of biopharmaceutical experience from start-up to large global pharma and targeted launch experience in Men's Health. Mr. Jaeger has been instrumental in developing our launch strategy for these assets, and we look forward to his continued strong leadership as we reach launch and beyond.

With our commercial leadership team in place, we have identified key areas on which to focus our efforts, including expanding product availability for our patients, as well as marketing and advertising to increase awareness for our products through multiple channels.

Expanding Product Availability for Patients

We have taken key steps to ensure that patients have proper access to therapy, including securing a license from the Ohio State Board of Pharmacy, allowing us to operate as a pharmaceutical wholesaler in our home state of Ohio. As we look to gain additional licenses, we are also making significant progress in identifying vendors and solidifying agreements with key players in the distribution channel, including third party logistics providers and wholesalers to serve our retail pharmacy customers nationwide.

In addition to the traditional retail pharmacy channel, our commercial team has identified telemedicine as a potential solution for select patients to access therapy without having to step into a healthcare provider's office. Telemedicine is helpful for remote patients, those with timing constraints, or those who may have difficulty scheduling an appointment with a specialist. This approach is particularly relevant for current BPH patients who may be eligible for ENTADFI®. We are in the process of identifying the right telemedicine partner for ENTADFI® and potentially other assets in our portfolio, so that our patients can benefit from this platform upon official launch.

In order to help patients access our products, we plan to partner with a hub provider to not only address the challenges that patients may have during the treatment journey, but also to help ease the administrative burden on healthcare providers. The payer coverage process is very complex and can be extremely time consuming for providers, and our goal in utilizing a hub will be to help providers navigate this process and help alleviate subsequent treatment delays for patients. Additionally, as many of our products are long-term medications, we will lean on our selected hub vendor to serve patients throughout the treatment journey and provide support to them and their prescribers, with an eye to optimizing revenue for Blue Water with recurring prescriptions.

Regardless of the channel our patients utilize to access our therapies, our commercial team recognizes that payer coverage and market access is critical to the success of any pharmaceutical launch. To this end, we recently signed an agreement with Advantage Point Solutions, LLC to support our market access strategy and to assist in formulary negotiations with key healthcare payers and pharmacy benefit managers for ENTADFI®. With their robust network of relationships, we are confident that they are the right partner for this endeavor and will help us secure placement on key formularies in the commercial and government sectors.

Increasing Product Awareness Through Marketing & Advertising

In addition to our patient- and provider-focused approach to ensure proper access to therapy, we are developing an extensive marketing and advertising strategy with industry leading organizations to support our commercial portfolio. This approach includes the creation of a robust sales team capable of reaching physicians nationwide, as well as the generation of powerful marketing material designed to maximize impact and drive sales.

In June 2023, we announced a collaboration with IQVIA to build our medical sales representative team, covering key geographies that account for a large percentage of prescriptions in target markets of urology and cardiology. We are in the process of finalizing the targeted launch plan for this team, but we believe they will be instrumental in the success of our products as they identify physicians across the country and increase awareness. We fully intend to provide our team with proper sales materials, including extensive disease state and product education, access to a robust customer relationship management software, updated prescribing data and trends, as well as effective marketing material to educate physicians.

In addition to establishment of our sales team with IQVIA, we have made significant progress on the marketing and advertising front through the signing of a Master Services Agreement with bfw Advertising Inc. (“bfw”) and generating an action plan for our commercial portfolio. Bfw has more than three decades of experience supporting life science companies of various sizes and stages, and we are working closely with them to generate new and effective marketing materials for our products, as well as improve on current materials for these products. With bfw, we look forward to rolling out patient-facing materials, website updates, social ads, targeted provider engagement, as well as materials to support our sales team with IQVIA, in the coming weeks and months.

To summarize, the last few months have certainly been an exciting time for Blue Water, filled with acquisitions, growth, and execution. Although we have made significant progress on our launch plans in a short period of time, we also look forward to achieving the key milestones outlined above and generating additional value for our shareholders.

We thank you for your continued support of Blue Water.

Sincerely,

Joseph Hernandez

Chairman and Chief Executive Officer

About ENTADFI®

ENTADFI® is an oral, once daily 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. 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 and pharmaceutical company focused on developing and commercializing transformational therapies to address significant health challenges globally. Headquartered in Cincinnati, OH, the Company 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 benign prostatic hyperplasia without the negative sexual side effects typically seen in patients on finasteride alone. The Company is also in the process of acquiring the approved therapies from WraSer, LLC, and Xspire Pharma, LLC, including ZONTIVITY® (reduction of thrombotic cardiovascular events in patients with myocardial infarction or with peripheral arterial disease), OTOVEL® (acute otitis media with tympanostomy tubes), CETRAXAL® (acute otitis externa), CONJUPRI® (hypertension), TREZIX™ (moderate to severe pain) and NALFON® (NSAID treatment for pain and inflammation). The Company also has a robust preclinical vaccine pipeline. Blue Water 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 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 S&P nanoparticle versatile virus-like particle 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. For more information about Blue Water, visit www.bwbioinc.com.

Cautionary Note Regarding 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 (including, without limitation, the anticipated benefits of the Company’s agreement with IQVIA, APS and bfw and the anticipated results of the Company’s sales and marketing efforts for its commercial stage products, each as described herein) 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 acquisitions of ENTADFI®, ZONTIVITY®, OTOVEL®, CETRAXAL®, CONJUPRI®, TREZIX™ and NALFON®; risks related to Blue Water’s ability to expand its business scope, commercialize ENTADFI® and integrate the assets and commercial operations being acquired from WraSer, LLC, and Xspire Pharma, LLC into Blue Water’s business; risks related to Blue Water’s ability to attract, hire and retain skilled personnel and establish an effective sales team; risks related to Blue Water’s ability to establish, maintain and optimize key third party commercial collaboration agreements (such as those with IQVIA, APS and bfw); risks related to the Company’s present need for capital to close its asset acquisitions, commercially launch the Company’s acquired products and have adequate working capital; risks related to the development of Blue Water’s vaccine candidates; 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; 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 commercial-stage pharmaceutical product or any product candidate under clinical development, there are significant risks in the development, regulatory approval and commercialization of pharmaceutical 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@bwbioinc.com