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 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 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 July 25, 2023, Blue Water Biotech, Inc., a Delaware corporation (the "Company"), issued a press release announcing that it has entered into an agreement with UpScriptHealth to generate a robust, online telemedicine platform to distribute the Company's benign prostatic hyperplasia asset, ENTADFI® (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 July 25, 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.

Blue Water Biotech, Inc.

Date: July 25, 2023

By: /s/ Joseph Hernandez
Joseph Hernandez
Chief Executive Officer

Exhibit 99.1

Blue Water Biotech Teams with UpScriptHealth to Launch Telemedicine Platform for Benign Prostatic Hyperplasia Asset, ENTADFI®

CINCINNATI, OH, July 25, 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 announced an agreement with UpScriptHealth ("UpScript") to generate a robust, online telemedicine platform to distribute Blue Water's benign prostatic hyperplasia ("BPH") asset, ENTADFI®.

Under this agreement, UpScript will build an online platform to support BPH patients throughout the prescription and coverage process, as well as provide eligible patients access to ENTADFI® mailed directly to their homes. UpScript, a leading provider of telehealth services, has over 20 years of experience generating effective, web-based campaigns for life science companies with a wide range of services, including virtual prescribing, coverage and benefit support, as well as long-term adherence support.

"Telehealth, with its increasing popularity in recent years, is a great opportunity to improve not only patient access to therapy, but improve patient lives throughout the entire treatment journey," said Joseph Hernandez, Chairman and Chief Executive Officer of Blue Water. "Together with UpScript and through this platform, intend to provide eligible BPH patients direct access to ENTADFI® online, minimizing the need for specialist visits and trips to the pharmacy that can be burdensome to patients. With UpScript's proven track record and unwavering dedication to easing patient challenges through telehealth solutions, we are thrilled to take this next step with UpScript and look forward to launching this campaign."

It is estimated about 55 million men in the United States have or are at risk for BPH, with affected patients suffering from challenges with urination flow, frequency, and urgency, along with sexual dysfunction in many cases. Through this online platform, existing BPH patients will be able to communicate with a healthcare provider online and may be eligible to receive ENTADFI® without the need for another specialist visit and can receive their prescription in the mail or through one of UpScript's partner pharmacies. This solution will be designed to not only increase access for ENTADFI® nationwide, but also offers patients a time-saving solution while still receiving administrative help during the coverage process through UpScript's benefit support capabilities.

This agreement with UpScript represents a milestone reached by Blue Water in its efforts to launch its commercial portfolio, highlighted by ENTADFI®, that was previously announced in a letter to shareholders from Mr. Hernandez earlier this month. With the official launch of ENTADFI® scheduled in the coming months, Blue Water's commercial team is executing on key strategies including sales force development, distribution capabilities, as well as marketing and advertising development.

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. 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 UpScriptHealth™

UpScriptHealth™ is a comprehensive, direct-to-consumer telehealth and virtual prescribing platform that is innovating the way customers get the medications they need. UpScriptHealth has been innovating telehealth for over 20 years and remains committed to improving the lives of consumers by providing immediate and long-term convenient access to medical therapies. We embody values of transparency and integrity that have strengthened our core philosophy of care. To learn more about UpScriptHealth, visit www.UpScriptHealth.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 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 UpScript, 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 UpScript, 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