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): August 10, 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 August 10, 2023, Blue Water Biotech, Inc., a Delaware corporation (the "Company"), issued a press release announcing that it has entered into an agreement with Copay Consultants, LLC to build copay assistance programs for the Company's commercial products, including ENTADFI® and ZONTIVITY® (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 August 10, 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: August 10, 2023

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

Exhibit 99.1

Blue Water Biotech and Copay Consultants Collaborate to Build Copay Assistance Programs for Blue Water's Commercial Products

CINCINNATI, OH, August 10, 2023 – Blue Water Biotech, Inc. ("Blue Water" or the "Company"), a biotechnology and pharmaceutical company spanning multiple sectors, today announced the signing of an agreement with Copay Consultants, LLC ("Copay Consultants") to build copay assistance programs for Blue Water's commercial products, including ENTADFI®, which was acquired in April and ZONTIVITY®, which is expected to be acquired in the coming weeks after the signing of an asset purchase agreement in June.

Copay Consultants team has over 40 years of combined experience in the life science industry, including creation of manufacturer sponsored patient savings programs, pharmacy adjudicated copay discount programs, direct to patient rebates, patient web enrollment and attestation services, patient messaging, among others. In this new effort, Blue Water's commercial team will work closely with Copay Consultants to design and implement a copay assistance program for eligible ENTADFI® and ZONTIVITY® patients.

"Oftentimes, getting a prescription and securing insurance coverage is only the first step in the process of a patient initiating therapy," said Joseph Hernandez, Chairman and Chief Executive Officer of Blue Water. "When patients arrive at the pharmacy and are exposed to high out of pocket costs, copay assistance programs like these can prove critical to ensuring those patients begin treatment. With our copay programs and through this collaboration with Copay Consultants, we are excited to show our commitment to patients across the country and their ability to afford our treatments."

After the acquisition of ENTADFI® in April and signing of an asset purchase agreement to acquire ZONTIVITY® in June, Blue Water management presented its commercial launch strategy in a letter to shareholders last month. Recent execution includes significant progress with Blue Water collaborators and vendors across sales, marketing, advertising, telehealth development, market access, and sample distribution. This new agreement with Copay Consultants is expected to help eligible patients lower the out of pocket costs associated with treatment and is another critical step towards the official launch of these products, expected in the coming months.

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 ZONTIVITY®

ZONTIVITY® is a once daily, oral treatment indicated for the reduction of thrombotic cardiovascular events for patients with a history of myocardial infarction (MI) or with peripheral arterial disease (PAD). ZONTIVITY® has been shown to reduce the rate of a combined endpoint of cardiovascular death, MI, stroke, and urgent coronary revascularization when used with aspirin and/or clopidogrel. More information about MI, PAD, and full ZONTIVITY® prescribing information can be found on the product website at https://zontivity.com/.

About Copay Consultants

Copay Consultants, LLC is a service provider in the marketing and patient access space within the life science industry. Working as an extension of marketing and market access teams, Copay Consultants develops manufacture sponsored savings programs catered to individual products, market trends and competitive landscape which provide affordable access for patients. For more information about Copay consultants, visit www.copayconsultants.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.

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 Copay Consultants) 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, market and other conditions, 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 Knipper, 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 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.

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