

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 31, 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 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 31, 2023, Blue Water Biotech, Inc., a Delaware corporation (the “Company”), issued a press release announcing that it has entered into an agreement with Knipper Health to manage the inventory and distribution of product samples to sales representatives for 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 July 31, 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 31, 2023

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

Blue Water Biotech and Knipper Health Join Forces to Distribute Samples for ENTADFI[®] and ZONTIVITY[®] to Physicians

CINCINNATI, OH, July 31, 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 Knipper Health, Inc. (“Knipper Health”) to manage the inventory and distribution of product samples to sales representatives for ENTADFI[®] and ZONTIVITY[®].

Knipper Health has more than 35 years of experience building and maintaining operations for healthcare clients, including sample management, custom pharmacy solutions and 3PL services. As part of Blue Water’s product roll-out plans, Knipper Health will oversee sample inventory and ship samples on request to the sales force in the field. This will help to expedite physicians’ initiation of therapy for their patients while increasing familiarity with the products.

“This agreement is another step toward placing our commercial products into the hands of physicians and the patients in need,” said Joseph Hernandez, Chairman and Chief Executive Officer of Blue Water. “We are moving forward with our aggressive timelines and will continue to provide updates on our launch progress. Most importantly is our collaboration with proven industry partners such as Knipper Health, that will help to make the product launches successful. These agreements and partnerships will be critical to ensure not only the successful launch of these products, but to maximize long term access to potentially life-saving medications for patients.”

Blue Water purchased ENTADFI[®] in April 2023, followed by an asset purchase agreement for six FDA-approved assets, including ZONTIVITY[®], that is expected to close later this year. Since the execution of those agreements, the Company has made significant commercialization progress with market access and distribution. Blue Water has executed agreements that cover market access and payor coverage, marketing and advertising, telehealth services generation and sales force development.

About ENTADFI[®]

ENTADFI[®] is a once daily, oral treatment for BPH that combines finasteride, a 5 α -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 Knipper Health

Knipper Health is a leading healthcare solutions company serving the pharmaceutical, biotechnology, and medical device industries for more than 35 years, with a focus on sample management and marketing, custom pharmacy solutions and 3PL services. Knipper has become the single source-provider of samples management services for many small, to large pharmaceutical customers. KnippeRx is a highly nimble, independent specialty pharmacy that serves both commercial and non-commercial needs. KnippeRx helps overcome the complex barriers to patient access by providing the shortest path from initiation of a prescription to delivery of essential therapy. Knipper 3PL provides storage and distribution of CRT, Cold Chain, Frozen, and DEA III-V products along with full order to cash, chargebacks, and contract management services.

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 agreements with Knipper, UpScript, IQVIA, APS and bfw and the anticipated results of the Company's sales and marketing efforts for its commercial stage products 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 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 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.

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