

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): June 21, 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 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 June 21, 2023, Blue Water Biotech, Inc., a Delaware corporation (the “Company”) issued a press release announcing its plans to establish a medical sales representative team with industry leader, IQVIA, to market the Company’s commercial portfolio, including recently acquired assets ENTADFI®, a treatment for benign prostatic hyperplasia, and ZONTIVITY®, a medication for the reduction of thrombotic cardiovascular events in patients with a history of myocardial infarction or with peripheral arterial disease (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 June 21, 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: June 21, 2023

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

Blue Water Biotech Collaborates with IQVIA to Build Medical Sales Representative Team to Market Commercial Product Portfolio

CINCINNATI, OH, June 21, 2023 - Blue Water Biotech, Inc. (“Blue Water” or the “Company”) (Nasdaq: BWV), a biotechnology and pharmaceutical company spanning multiple sectors, today announced plans to establish a medical sales representative team with IQVIA to market Blue Water’s commercial portfolio. This portfolio is highlighted by ENTADFI[®], a treatment for benign prostatic hyperplasia, and ZONTIVITY[®], a medication for the reduction of thrombotic cardiovascular events in patients with a history of myocardial infarction or with peripheral arterial disease.

In this collaboration, IQVIA and Blue Water will jointly work to build a sales team for Blue Water’s commercial products, covering key geographies that account for a large percentage of prescriptions in target markets, including urology and cardiology. Blue Water and IQVIA have agreed to commence certain activities on a provisional basis and are working towards finalizing a definitive agreement. Upon execution of a definitive agreement, Blue Water expects that IQVIA representatives and Blue Water’s commercial team will seek to identify high-volume prescribers in key markets to maximize uptake and socialization of Blue Water products. IQVIA, a global provider of data analytics and solutions for the development of robust medical sales representative teams to support emerging life science companies, has a proven track record of establishing effective medical sales teams.

“This collaboration with IQVIA is a promising step towards the launch of ENTADFI[®] and the six assets we are acquiring,” said Joseph Hernandez, Chairman and Chief Executive Officer of Blue Water. “With decades of experience helping companies commercialize and market their products, we are thrilled to collaborate with IQVIA to build out our sales team and educate providers on the benefits of our products to get patients access to therapies they need.”

In addition to the purchase of ENTADFI[®] in April 2023, Blue Water recently signed an Asset Purchase Agreement on June 13, 2023 for the purchase of six FDA-approved assets across multiple indications, including cardiology, otic infections, and pain management. Blue Water management intends to work closely with IQVIA to develop a strategy to market Blue Water’s portfolio of assets to physicians across the United States.

About Blue Water Biotech

Blue Water Biotech, Inc. is a biological and pharmaceutical technology company focused on developing and providing 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 also has a robust 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 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 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 enter into a definitive agreement with IQVIA and optimize its collaboration with IQVIA; 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.

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