

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 6, 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 8.01 Other Events.**

On July 6, 2023, Blue Water Biotech, Inc., a Delaware corporation (the “Company”), issued a press release announcing that the Ohio State Board of Pharmacy has granted the Company a license to operate as a pharmaceutical wholesaler in the State of Ohio (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 6, 2023.](#)

104 Cover Page Interactive Data File (embedded within the Inline XBRL document).

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**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 6, 2023

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

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**Blue Water Biotech Secures License from Ohio State Board of Pharmacy to Operate as Pharmaceutical Wholesaler for its FDA Approved Products**

*First state license is a key achievement as Blue Water continues to expand its business into commercial activities*

**CINCINNATI, OH, July 6, 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 that the Ohio State Board of Pharmacy has granted Blue Water a license to operate as a pharmaceutical wholesaler in the State of Ohio.

Headquartered in Cincinnati, OH, Blue Water recently acquired multiple FDA-approved pharmaceutical assets across various indications, including urology, cardiology, inner ear infections, and pain management to establish itself as a commercial stage pharmaceutical company. This license allows Blue Water to conduct business in the State of Ohio and is the first granted to the Company since its establishment as a commercial state company.

“Securing this license in our home state is a very important first step for patients and providers to access Blue Water products nationwide,” said Joseph Hernandez, Chairman and Chief Executive Officer of Blue Water. “We are keenly focused on building out our sales team and aligning ourselves with the right commercial partners as we prepare for launch, and these licenses are critical for us to deliver on our proposed strategies. We look forward to securing additional state licenses and expanding further to maximize availability and access to our products.”

In April 2023, Blue Water acquired ENTADFI<sup>®</sup>, an FDA-approved treatment for benign prostatic hyperplasia (“BPH”) that counteracts negative sexual side effects seen in men on alternative BPH therapies. Following this acquisition, Blue Water recently announced an Asset Purchase Agreement with WraSer, LLC and Xspire Pharma, LLC for the purchase of six FDA-approved assets across various treatment areas.

In recent months, Blue Water has signed key agreements to work towards commercialization of its products, including an agreement with IQVIA to establish a medical sales representative team to market Blue Water’s products. Additionally, the Company yesterday announced the signing of a Master Services Agreement with bfw Advertising Inc. to generate marketing and advertising material for its portfolio and expects to launch these materials in the coming months. These agreements, along with the granted license in Ohio and any future state licenses, will help ensure proper awareness and access to all of Blue Water’s products.

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## **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<sup>®</sup>, 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](http://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 Ohio license, statements about the Company's plans to secure future state licenses and the anticipated results of the Company's sales and market efforts, 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<sup>®</sup>, ZONTIVITY<sup>®</sup>, OTOVEL<sup>®</sup>, CETRAXAL<sup>®</sup>, CONJUPRI<sup>®</sup>, TREZIX<sup>™</sup> and NALFON<sup>®</sup>; risks related to Blue Water's ability to expand its business scope, commercialize ENTADFI<sup>®</sup> 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;; 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 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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