

**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): April 12, 2023

Blue Water Vaccines 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 7.01 Regulation FD Disclosure.

On April 12, 2023, Blue Water Vaccines Inc. (the “Company”) issued a press release announcing the signing of a Sponsored Research Agreement with The University of Texas Health Science Center at San Antonio to initiate a non-human primate study for a live attenuated, orally delivered chlamydia vaccine. A copy of the press release is attached hereto as Exhibit 99.1.

The foregoing (including Exhibit 99.1) is being furnished pursuant to Item 7.01 and will not be deemed to be filed for purposes of Section 18 of the Securities and Exchange Act of 1934, as amended (the “Exchange Act”), or otherwise be subject to the liabilities of that section, nor will it be deemed to be incorporated by reference in any filing under the Securities Act of 1933, as amended, or the Exchange Act.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits

99.1	Press Release dated April 12, 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.

Date: April 12, 2023

Blue Water Vaccines Inc.

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

Blue Water Vaccines Announces Signing of Sponsored Research Agreement with The University of Texas Health Science Center at San Antonio to Initiate Non-Human Primate Study for Live Attenuated, Orally Delivered Chlamydia Vaccine

CINCINNATI, OH, April 12 2023 -- Blue Water Vaccines Inc. (“BWV” or “Blue Water Vaccines” or the “Company”), a biopharmaceutical company developing transformational vaccines to address significant global health challenges, today announced the signing of a Sponsored Research Agreement (the “Agreement”) with The University of Texas Health Science Center at San Antonio (“UT Health Science Center San Antonio”) to fund a non-human primate (“NHP”) study to evaluate the efficacy of BWV-401, a live attenuated, orally delivered Chlamydia vaccine.

In November 2022, BWV signed an exclusive, global license agreement with UT Health Science Center San Antonio for the development of this novel vaccine candidate, BWV-401, to prevent Chlamydia infection. BWV-401 utilizes a modified strain of Chlamydia to colonize in the gastrointestinal tract and has produced transmucosal protection against genital tract Chlamydia infection in mouse models without altering the gut microbiota. In this new effort, BWV will fund an NHP study to further evaluate the efficacy of BWV-401 and provide additional support for development towards human clinical trials.

Often regarded as the gold standard animal model for drug development and approval, NHP studies allow researchers to assess safety and efficacy of vaccines in human-like models without completing full, robust human clinical trials. In this upcoming study, NHPs will be vaccinated with BWV-401 and subsequently challenged against Chlamydia to validate the hypothesis that, along with being a safe, this vaccine, when delivered orally, is capable of eliciting an effective immune response in the genital tract and can protect against Chlamydia infection.

“We are thrilled to initiate this study with our partners at UT Health Science Center San Antonio for BWV-401,” said Joseph Hernandez, Chairman and Chief Executive Officer of Blue Water Vaccines. “There remains a high unmet need for an efficacious Chlamydia vaccine to prevent the millions of infections seen around the world each year. We look forward to completing this study and moving one step closer towards clinical development of this novel vaccine.”

According to the CDC, Chlamydia is the most frequently reported bacterial STI in the United States, with about 1.6 million new cases reported in 2020 alone. Globally, the WHO estimates about 129 million new cases of Chlamydia each year and may be an underrepresentation given many cases are asymptomatic and low availability of diagnostic testing in low- and middle-income countries. Currently, there is no vaccine available to prevent Chlamydia infection, and the main treatment is through antibiotic regimens with the possibility of reinfection after antibiotics have treated the disease. If undetected or left untreated, Chlamydia represents a major cause of pelvic inflammatory disease and infertility in women.

About Blue Water Vaccines

Blue Water Vaccines Inc. is a biopharmaceutical company focused on developing transformational vaccines to address significant health challenges globally. Headquartered in Cincinnati, OH, the Company 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. The Company is developing a universal flu vaccine that will provide protection from all virulent strains in addition to licensing a novel norovirus (NoV) S&P nanoparticle versatile virus-like particle (VLP) vaccine platform from Cincinnati Children's to develop vaccines for multiple infectious diseases, including norovirus/rotavirus and malaria, among others. Additionally, Blue Water Vaccines is developing a *Streptococcus pneumoniae* (*pneumococcus*) vaccine candidate, designed to specifically prevent the highly infectious middle ear infections, known as Acute Otitis Media (AOM), in children, and prevention of pneumonia in older people at risk for contracting pneumococcal pneumonia, a significant unmet medical need. The advantage of this technology includes a serotype independent mucosal immunity that prevents colonization in the upper respiratory tract as well as systemic immunity that can confer serotype independent against invasive pneumococcal disease. The Company is also 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, visit www.bluewatervaccines.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 BWV'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 the development of BWV'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. BWV does not undertake an obligation to update or revise any forward-looking statement. Investors should read the risk factors set forth in BWV'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 BWV'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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