

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): October 11, 2022

**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

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 October 11, 2022, Blue Water Vaccines, Inc. (the “Company”) issued a press release announcing plans to investigate the ability of BWV-201, a *Streptococcus pneumoniae* vaccine candidate for acute otitis media prevention, to also protect against non-invasive pneumococcal pneumonia at the World Vaccine Congress in Barcelona.

The full text of the press release is furnished as Exhibit 99.1 to this Form 8-K and is incorporated by reference in this Item 7.01.

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	<a href="#">Press Release, dated October 11, 2022</a>
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 Vaccines Inc.**

Date: October 11, 2022

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

## Blue Water Vaccines Announces Plans to Evaluate Efficacy of *Streptococcus pneumoniae* Vaccine Candidate Against Pneumococcal Pneumonia at the World Vaccine Congress in Barcelona

CINCINNATI, OH, October 11, 2022 -- 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 plans to investigate the ability of BWV-201, a *Streptococcus pneumoniae* vaccine candidate for acute otitis media (“AOM”) prevention, to also protect against non-invasive pneumococcal pneumonia at the World Vaccine Congress in Barcelona.

While *Streptococcus pneumoniae* is commonly found in the nose and throat of healthy individuals, overgrowth and spread of the bacteria can result in pneumococcal disease. Non-invasive forms of pneumococcal disease include AOM, sinusitis, and pneumococcal pneumonia, while invasive forms include bacteremia, sepsis, and pneumococcal meningitis. BWV’s new development plan aims to assess the efficacy of BWV-201 in protecting individuals against non-invasive pneumococcal pneumonia.

BWV-201 is a live attenuated bacterial vaccine candidate developed for the prevention of AOM in children caused by *Streptococcus pneumoniae*. New data, based on experiments at St. Jude Children’s Research Hospital, suggests that BWV-201 may also provide protection against pneumococcal pneumonia by limiting the ability of *Streptococcus pneumoniae* to infect the lungs.

While conjugate and polysaccharide vaccines are available to protect against pneumococcal disease, protection is mainly limited to invasive disease. Efficacy rates of these vaccines against pneumococcal pneumonia are historically only between 0% and 50%, as these vaccines are administered intramuscularly and elicit a strong systemic response, but poor protection at the mucosal surface where pneumonia infection begins. Additionally, these vaccines only provide protection against serotypes included in the vaccine, ranging from 13 to 23 serotypes. By administering the modified live bacteria intranasally, BWV-201 is designed to elicit a strong mucosal immune response, regardless of capsular polysaccharide serotype.

“While current pneumococcal vaccines have demonstrated excellent efficacy against invasive pneumococcal disease historically, pneumococcal pneumonia remains a significant unmet medical need,” said Joseph Hernandez, Chairman and Chief Executive Officer of Blue Water Vaccines. “With this new data, we believe our vaccine can provide protection across all *Streptococcus pneumoniae* strains and eliminate the need for antibiotic treatment associated with pneumococcal pneumonia. We are excited to further develop BWV-201 for this new indication and look forward to addressing this need.”

According to the Centers for Disease Control and Prevention, non-invasive pneumococcal pneumonia causes an estimated 150,000 hospitalizations each year in the United States alone. Despite vaccination efforts with traditional pneumococcal vaccines, the American Lung Association reports that adults over 65 years old are at 6.1 times greater risk for pneumonia infection and over 10 times more likely to be hospitalized with pneumococcal pneumonia versus healthy adults.

### 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, and St. Jude Children’s Hospital. 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. For more information, visit [www.bluewatervaccines.com](http://www.bluewatervaccines.com).

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## 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 for the fiscal year ended December 31, 2021, filed with the Securities and Exchange Commission (the “SEC”) on March 31, 2022, Quarterly Report on Form 10-Q for the quarter ended June 30, 2022, filed with the SEC on August 15, 2022 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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