

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): March 22, 2022

Blue Water Vaccines Inc.
(Exact name of registrant as specified in its charter)

Delaware

001-41294

83-2262816

(State or other jurisdiction of incorporation)

(Commission File Number)

(IRS Employer Identification No.)

201 E. Fifth Street, Suite 1900 Cincinnati, Ohio

45202

(Address of principal executive offices)

(Zip Code)

Registrant's telephone number, including area code: (513) 620-4101

Not Applicable

(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 (see General Instruction A.2. below):

- 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 March 22, 2022, Blue Water Vaccines Inc. (the “Company”) issued a press release announcing the publication by the Company’s licensing partner, Cincinnati Children’s Hospital Medical Center, of a research paper in *Nano Research* relating to the Company’s S&P vaccine platform.

A copy of the press release is attached as Exhibit 99.1 to this Current Report on Form 8-K and is incorporated herein by reference.

Special Note Regarding Forward-Looking Statements

This Current Report on Form 8-K contains “forward-looking statements” within the meaning of Section 27A of the Securities Act and Section 21E of the Exchange Act. These statements relate to future events and involve known and unknown risks, uncertainties and other factors which may cause the Company’s actual results, performance or achievements to be materially different from any future results, performances or achievements expressed or implied by the forward-looking statements. In some cases, you can identify forward-looking statements by terms such as “may”, “will”, “should”, “could”, “would”, “expects”, “plans”, “anticipates”, “believes”, “estimates”, “projects”, “predicts”, “potential” and similar expressions intended to identify forward looking statements. These statements reflect the Company’s current views with respect to future events and are based on assumptions and subject to risks and uncertainties. Given these uncertainties, you should not place undue reliance on these forward-looking statements. Also, these forward-looking statements represent the Company’s estimates and assumptions only as of the date of this Current Report on Form 8-K

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits

Exhibit Number	Description of Exhibit
99.1	<u>Press Release, dated March 22, 2022</u>

SIGNATURE

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

Date: March 22, 2022

Blue Water Vaccines Inc.

/s/ Joseph Hernandez

Joseph Hernandez

Chief Executive Officer

Blue Water Vaccines Announces Publication in *Nano Research* Supporting Novel S&P Vaccine Platform Versatility

- Blue Water Vaccines has exclusive, global licensing rights to Cincinnati Children’s Hospital Medical Center’s novel virus-like particle (VLP) vaccine platform.
- The data supports BWV’s ongoing development of a transformational universal influenza vaccine, as well as a rotavirus & norovirus vaccine to prevent gastroenteritis infection.

CINCINNATI, OH, March 22, 2022 -- Blue Water Vaccines Inc. (“BWV” or “Blue Water Vaccines” or “the Company”) a biopharmaceutical company developing vaccines, today announced that their licensing partner, Cincinnati Children’s Hospital Medical Center, or CCHMC, has published a research paper entitled “Bioengineered pseudovirus nanoparticles displaying the HA1 antigens of influenza viruses for enhanced immunogenicity” in *Nano Research*. The company’s lead vaccine programs are focused on developing transformational and novel vaccines against various infectious diseases, including influenza and gastroenteritis by norovirus or rotavirus infection.

The company’s norovirus shell and protrusion (S&P) platform is currently being utilized to develop BWV-301, a vaccine for gastroenteritis caused by norovirus or rotavirus infection. This latest publication highlights the versatility of the S&P platform beyond norovirus / rotavirus application and supports BWV’s exploration of utilizing the novel S&P platform to develop vaccine candidates against H1, H3, and Flu B infections.

According to Ming Tan, Ph.D., the principal investigator of this study, “Successful creation of HA1 influenza antigen PVNPs is a critical step forward in the development of a stable, durable flu vaccine.” He added, “This platform will allow us to investigate the immunogenicity of pseudovirus nanoparticles (PVNPs) displaying various antigenic combinations and assess the potential effectiveness of each.”

The research describes new technology developed to generate a unique HA1 norovirus based PVNP that displays the receptor-binding HA1 antigens of influenza viruses (IVs). These PVNPs displaying the HA1 antigens react with HA-specific antibodies and can be used as a new reagent for influenza virus studies. Moreover, the proprietary PVNPs provide a platform framework for designing multiple potential vaccine candidates in addition to influenza, including the norovirus/rotavirus vaccine candidate currently in the company’s pipeline.

“This study is a great step forward for our S&P platform to develop novel vaccines across a wide range of infections, including influenza and gastroenteritis, which both represent significant global health burdens that need effective management through improved vaccines,” said Joseph Hernandez, CEO of BWV. “With our partner at CCHMC, we look forward to the next stage of development of this novel platform and exploration of various vaccine development applications.”

In July 2021, Blue Water Vaccines entered an exclusive, global licensing agreement with CCHMC to develop vaccines for multiple infectious diseases utilizing the latter’s novel virus-like particle (VLP) vaccine platform. The platform leverages norovirus capsid proteins to present foreign antigens for immune enhancement. This synergistic partnership leverages CCHMC’s scientific expertise for BWV’s vaccine development.

According to the World Health Organization, there are normally more than 1 billion influenza infections leading to 290,000 to 650,000 deaths each year, even with available vaccination efforts. Current influenza vaccines are incredibly limited, relying on annual review and potential reformulation based upon the predicted circulation of specific strains. Additionally, the Centers for Disease Control and Prevention reports that viral gastroenteritis infections cause approximately 200,000 deaths in children worldwide each year. While there are available vaccines for rotavirus infection, there are currently no approved vaccines for norovirus infection prevention.

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 (CCHMC), 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 CCHMC 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.

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, including, but not limited to BWV-301; 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 registration statement on Form S-1 relating to its initial public offering, initially filed with the Securities and Exchange Commission (the "SEC") on October 10, 2021, as amended, 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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