

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): May 25, 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

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.**

Attached as Exhibit 99.1 to this Current Report is the form of presentation that Blue Water Vaccines Inc. (the “Company”) intends to use in connection with certain meetings and presentations beginning on May 25, 2022 at the H.C. Wainwright Global Investment Conference in Miami, Florida.

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="#">Presentation, dated May 25, 2022</a>
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)

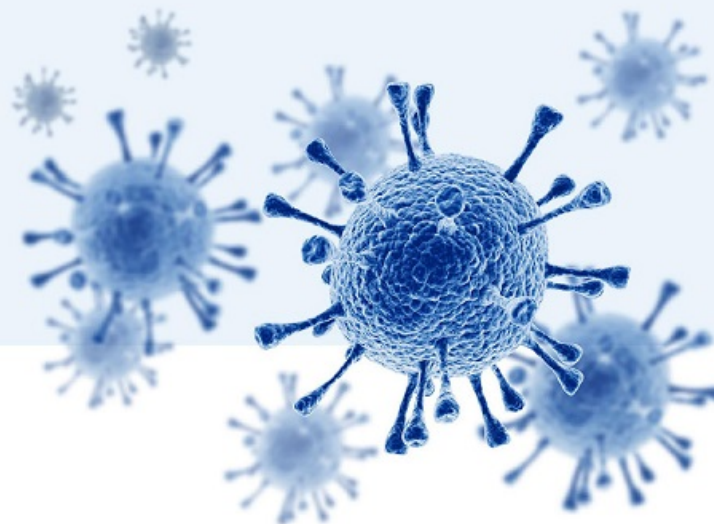
**SIGNATURE**

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.

Date: May 25, 2022

**Blue Water Vaccines Inc.**

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



**May 25, 2022**

NASDAQ: BWV

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The Presentation (the "Presentation") has been prepared by Blue Water Vaccines, Inc. (the "Company"). Certain information contained herein has been derived from sources prepared by third parties. While such information is believed to be reliable for the purposes used herein, the Company makes no representation or warranty with respect to the accuracy of such information.

This Presentation does not constitute an offer to sell, or the solicitation of an offer to buy, any securities of the Company in any jurisdiction, domestic or foreign, where the offer, solicitation or sale is not permitted or would be unlawful prior to registration or qualification under the securities laws of any such state or jurisdiction.

**FORWARD LOOKING STATEMENTS:**

Certain statements in this presentation (the "Presentation") has been prepared by Blue Water Vaccines, Inc. (the "Company"). This presentation contains 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 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, 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.

**SCIENCE. INNOVATION. IMMUNITY.**

**We believe science innovation improves lives. That's why we are researching and developing transformational vaccines to prevent infectious diseases worldwide.**

# BWV Highlights

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**Broad and diverse vaccine pipeline:**  
Novel preclinical vaccine candidates

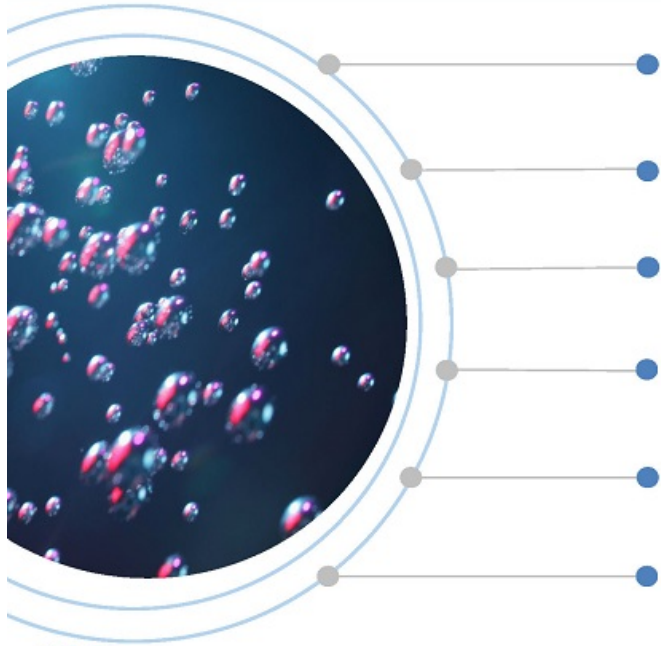


**Esteemed Collaborators:**  
University of Oxford,  
Cincinnati Children's,  
St. Jude Children's  
Research Hospital



**Secured Funding:**  
Recent IPO and PIPE  
provides lengthened  
cash runway for  
development

# Overview



**Broad and Diverse Vaccine Pipeline:** Novel preclinical vaccine candidates

**Proprietary Versatile Vaccine Platform:** POC data, multi-valent, scalable, flexible discovery engine with broad therapeutic capabilities

**Lead Vaccine Candidates:** Universal and H1 Influenza vaccine candidates utilizing proprietary epitopes of limited variability (ELV) that remain present through viral mutation

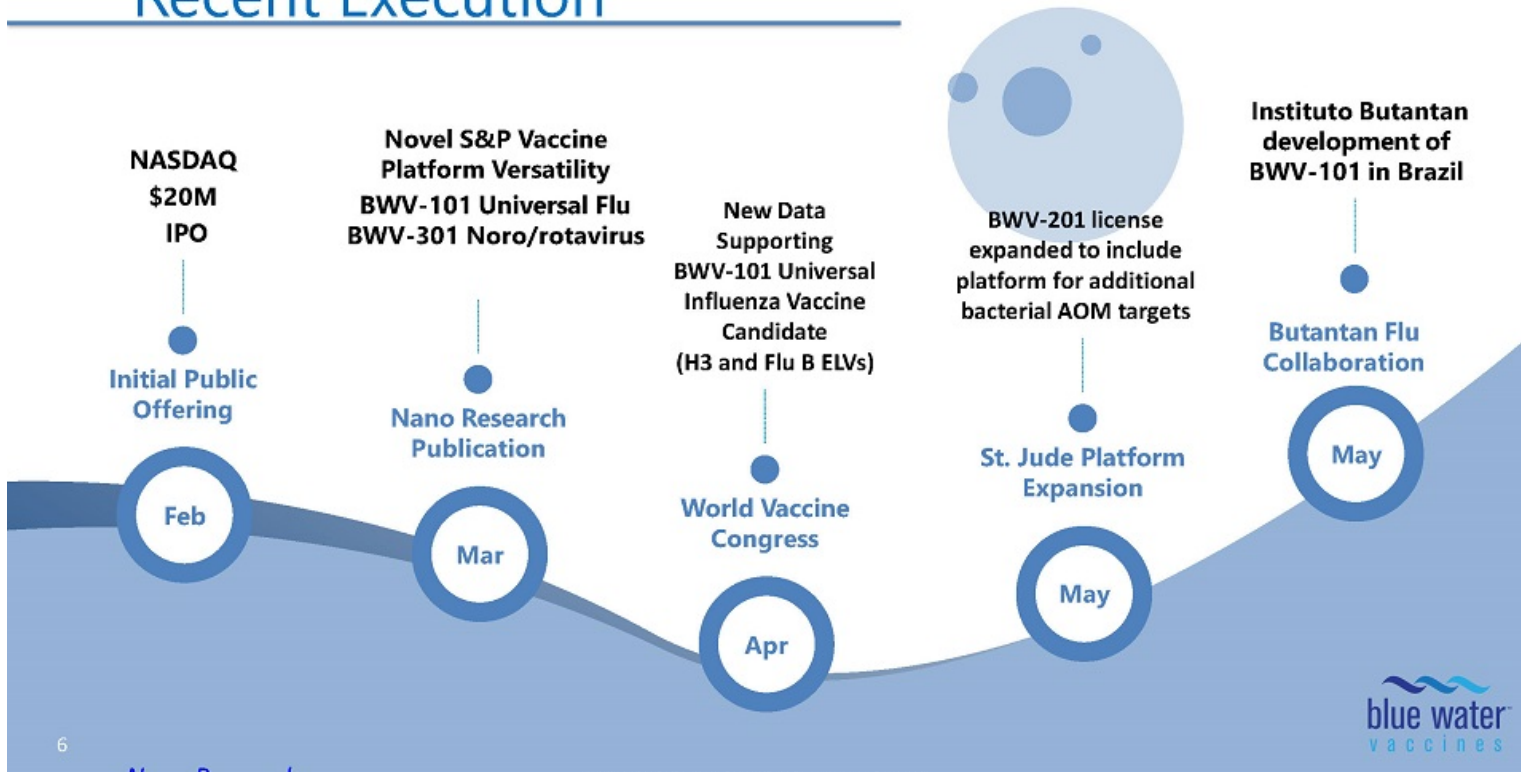
**AOM Prevention Candidate:** Targeting *Streptococcus pneumoniae* to prevent AOM utilizing an intranasally delivered proprietary live-attenuated strain

**Esteemed Collaborators:** University of Oxford, Cincinnati Children's, St. Jude Children's Research Hospital




**Opportunistic Business Model:** Exclusive licenses of assets and platforms, broad business development, opportunistic growth and expansion



# Recent Execution



# Novel Vaccine Pipeline

Infectious Disease Program	Candidate	Preclinical	Phase 1	Collaborator
Universal Flu				
H1 pre-pandemic				
S. pneumo induced AOM (intranasal)				
Norovirus / Rotavirus				
Norovirus / Malaria				

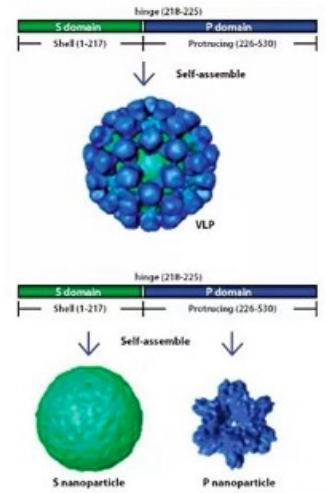
# Versatile Nanoparticle VLP Vaccine Platform

Our novel Shell and Protrusion (S&P) norovirus platform  
combines 2 or more immunogenic components:  
a norovirus antigen + at least one additional antigen = novel vaccines

Discovery Engine:  
potentially stable,  
flexible,  
cost-effective  
nanoparticles

POC:  
animal models  
showed strong  
enhanced  
immunogenicity

Broad therapeutic  
capabilities  
&  
Partnering  
opportunities



## Need for broad protection flu vaccine

- Current annual flu vaccine effectiveness is up to 50%
- 1 billion influenza infections each year, 3 – 5 million of which are considered severe; 290,000 to 650,000 deaths per year
- Influenza A&B cause most of human illness each flu season

## Differentiated Approach

- Global license with University of Oxford
- Mathematical model for epitope identification
- Epitopes of limited variability (ELV's) are naturally immunogenic and cross-reactive
- ELV's are ideal vaccine targets for broad, long-term protection

## Current Status

- BWV-101: Universal flu (H1, H3, Flu B)
- BWV-102: H1 pre-pandemic flu
- POC data for H1N1 published
- H3 and Flu B data presented at the World Vaccine Congress
- Provisional patents have been filed for H3N2 and Flu B ELVs

Influenza  
BWV-101  
BWV-102

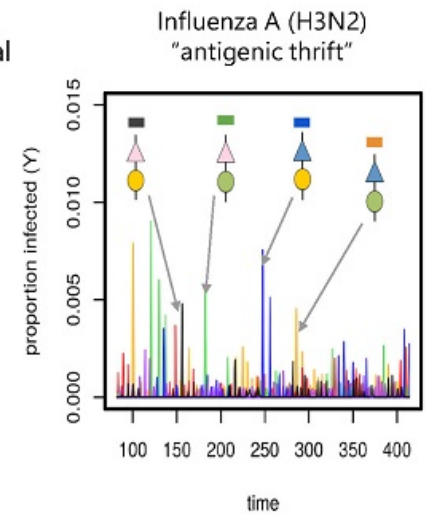
## Candidates

Influenza A H1N1:  
"OREO"

Influenza A H3N2:  
"INDY"  
"MAIZ"

Influenza B  
(Yamagata & Victoria):  
"TATI"

- Mice data demonstrated cross-reactive immune response in historical influenza strains such as H10N3 (bird flu), and H5NX, H7NX, and H9NX
- Two epitopes with either 4 or 6 variants. Currently generating additional neutralization data
- One epitope in 7 variants to cover the variability seen across these two lineages.



## Impact / Need

- Norovirus is the most common cause of acute gastroenteritis, 700 million cases annually.
- Rotavirus causes an estimated 111 million episodes of diarrhea
- Rotavirus is the most common cause of diarrheal disease among infants and young children
- No norovirus vaccine is available to date

## BWV's Differentiated Approach

- Our S&P platform was co-invented by Xi Jason Jiang, Ph.D., and Ming Tan, Ph.D., of the Division of Infectious Disease at the Cincinnati Children's
- Provides two distinct VLP options allowing for multiple delivery pathways
- Allows for single or multi-antigen presentation

## Current Status

- Preclinical data from gnotobiotic pig studies showed BWV-301 prevented severe gastroenteritis and reduces viral shedding
- Preclinical mouse sera after immunization with the S<sub>60</sub>-VP8\* nanoparticle exhibited higher neutralizing activity

# Norovirus- Rotavirus BWV-301

## Need for broad protection vaccine

- 5 million cases of AOM in the United States annually
- Estimated \$4.3 billion USD is spent on AOM treatment each year in the United States alone
- Complications from AOM include sensorineural hearing loss (SNHL)

## Differentiated Approach

- Global license with St. Jude Children's Research Hospital
- BWV-201 is a live attenuated serotype-independent vaccine
- Intranasal delivery
- Production of vaccine is straightforward; utilizes the entire bacterium

## Current Status

- Research funded by BWV to evaluate the viability of this vaccine platform to potentially provide protection against multiple pathogens including, non-typeable *Haemophilus influenzae* (NTHi)
- License expansion, provisional patent filed

# Bacterial Induced- AOM BWV-201

# BWV Summary & Conclusion

**1**

**Developing a broad portfolio of vaccine candidates**

*Influenza, AOM induced s. pneumo, noro-rotavirus*

**2**

**New ELV data for universal influenza**

*H3 & Flu B ELV data presented at WVC*

**3**

**Recent expansion of St. Jude License for BWV-201**

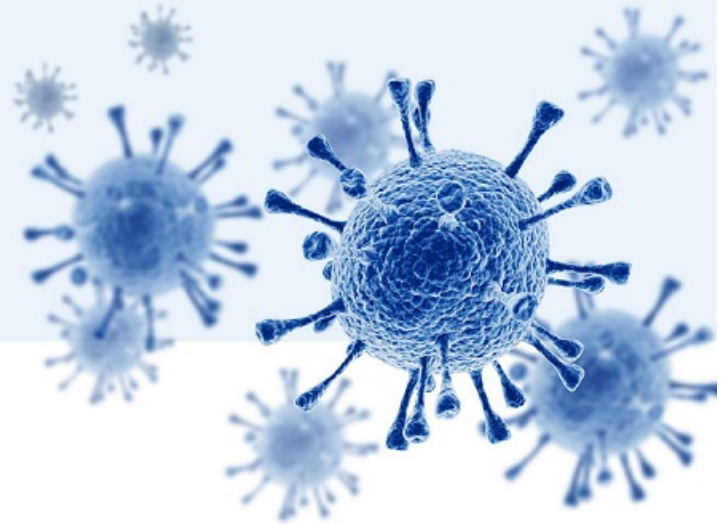
*Potential to provide broad coverage of AOM causing pathogens*

**4**

**Secured Cash Runway to support ongoing development**

*\$20m IPO and \$8m PIPE*





Thank you!

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