

This free writing prospectus relates to the proposed public offering of shares of common stock, par value \$0.00001 per share, and warrants of Blue Water Vaccines, Inc. (the "Company") which are being registered on a Registration Statement on Form S-1, as amended (File No. 333-260137) (the "Registration Statement"). This free writing prospectus should be read together with the preliminary prospectus dated January 6, 2022 included in that Registration Statement which can be accessed through the following link:

[https://www.sec.gov/Archives/edgar/data/0001782107/000121390022000991/fs12022a5\\_bluewatervac.htm](https://www.sec.gov/Archives/edgar/data/0001782107/000121390022000991/fs12022a5_bluewatervac.htm)

The Company has filed the Registration Statement (including a prospectus) with the Securities and Exchange Commission (the "SEC") for the offering to which this communication relates. Before you invest, you should read the prospectus in that Registration Statement (including the Risk Factors contained therein) and other documents that the Company has filed with the SEC for more complete information about our company and this offering. You may get these documents for free by visiting EDGAR or the SEC web site at [www.sec.gov](http://www.sec.gov). Alternatively, the Company, any underwriter or any dealer participating in the offering will arrange to send you the prospectus if you request it from Maxim Group LLC, 300 Park Avenue, 16th Floor, New York NY 10022 by calling 212-895-3745.



## Corporate Overview

*Developing Transformational  
Vaccines*



#### Disclaimer

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 purport to contain all of the information that may be required to evaluate a possible transaction.

The Company has filed a registration statement on Form S-1, as amended (Registration No. 333-260137) with the Securities and Exchange Commission ("SEC"). The offering to which this Presentation will be made is pursuant to a prospectus included in the registration statement after the registration statement has been declared effective by the SEC. Before you invest, you should read the registration statement and the related prospectus and the other documents that we have filed with the SEC for more complete information about us and the offering. You may get these documents for free by visiting EDGAR on the SEC's website at [www.sec.gov](http://www.sec.gov).

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. The securities of the Company have not been registered under the Securities Act or any other applicable securities law. The Company's securities have not been approved or disapproved by the SEC or any other regulatory or governmental authority, nor have any of the foregoing passed upon the accuracy or adequacy of the information presented. Any representation to the contrary is a criminal offense.

Statements contained in this Presentation relate to the historical experience of the Company's founders, officers, directors or their affiliates. An investment in the Company is not an investment in any of their past investments, companies or funds affiliated with them. The historical results of these investments, companies or funds is not necessarily indicative of future performance of the Company.



#### Forward-Looking Statements

This Presentation and any accompanying oral presentation contains forward-looking statements within the meaning of federal securities law and are subject to certain risks and uncertainties inherent in the Company's business that could cause actual results to vary. These forward-looking statements appear in a number of places throughout this Presentation and include statements regarding our intentions, beliefs, projections, outlook, analyses or current expectations concerning, among other things; our ongoing and planned product development; the timing of, and our ability to make, regulatory filings and obtain and maintain regulatory approvals for our product candidates, as applicable; our intellectual property position; the degree of clinical utility of our products; our ability to develop commercial functions; our results of operations; cash needs; financial condition, liquidity, prospects, growth and strategies; the industry in which we operate; and the trends that may affect the industry or us.

We may, in some cases, use terms such as "believes," "estimates," "anticipates," "expects," "predicts," "plans," "intends," "possible," "potential," "may," "could," "might," "will," "should," "would," "approximately" or other words that convey uncertainty of future events or outcomes to identify these forward-looking statements. Although we believe that we have a reasonable basis for each forward-looking statement contained in this Presentation, we caution you that forward-looking statements are not guarantees of future performance and that our actual results of operations, financial condition and liquidity, and the development of the industry in which we operate may differ materially from the forward-looking statements contained in this Presentation.

You should also read carefully the factors described in the "Risk Factors" section and other parts of any prospectus that is distributed in order to better understand the risks and uncertainties inherent in our business and underlying any forward-looking statements. As a result of these factors, we cannot assure you that the forward-looking statements in this Presentation will prove to be accurate. Furthermore, if our forward-looking statements prove to be inaccurate, the inaccuracy may be material. In light of the significant uncertainties in these forward-looking statements, you should not regard these statements as a representation or warranty by any person that we will achieve our objectives and plans in any specified timeframe, or at all. Any forward-looking statements that we make in this Presentation speak only as of the date of such statement, and we undertake no obligation to update such statements to reflect events or circumstances after the date of this Presentation or to reflect the occurrence of unanticipated events.

# Accomplished Management Team and Board of Directors

*Led by experienced entrepreneurs who bring sustained records of successfully leading innovation and commercialization*



## Joseph Hernandez

Founder, Chairman & Chief Executive Officer

- Founder, Chairman, Blue Water Acquisition Corporation, (now Clarus, CRXT); Founder, Chairman Noachis Terra, Inc. (Oragenics, Inc)
- M.Sc., Chronic Disease Epidemiology Student, Yale; MBA, University of Florida



## Andrew Skibo

Head Biologic Operations

- Biological Manufacturing expertise
- Former, EVP, Operations, AstraZeneca/MedImmune
- M.S., Chemical Engineering, Massachusetts Institute of Technology



## Ronald Cobb, Ph.D.

Head of Science and Discovery

- Vaccine development expertise
- Former CSO, Ology Bioservices
- Ph.D, Biochemistry, Medical College of Georgia



## Erin Henderson

Chief Business Officer

- Administrative, corporate and stakeholder relations expertise
- Former Managing Principal, The Aetos Group
- B.S., Chemical Engineering, Auburn University



## Jon Garfield

Chief Financial Officer

- Financial and M&A expertise
- Prior big four accounting firm experience
- B.B.A, Accounting, University of Texas at Austin

## Post IPO Board of Directors

### Kimberly Murphy

Board of Directors at Oragenics, Inc (NYSE: OGEN) and Blue Water Acquisition Corp. (NASDAQ: BLUW)

### James Sapirstein

President & CEO, AzurRx Biopharma (NASDAQ: AZRX)

### Allan Shaw

CFO, Portage Biotech Inc. (NASDAQ: PRTG)

### Michael Venerable

CEO, CincyTech



# Partnered with Renowned Leaders



**Sunetra Gupta, Ph.D.**

Co-Inventor, Universal Influenza vaccine  
Department of Zoology, University of Oxford.



**Xi Jason Jiang, Ph.D.**

Co-Inventor, S & P Particle VLP Platform,  
Norovirus-Rotavirus vaccine  
Professor, University of Cincinnati,  
Department of Pediatrics



**Ming Tan, Ph.D.**

Co-Inventor, S & P Particle VLP Platform,  
Norovirus-Rotavirus vaccine  
Assistant Professor, University of  
Cincinnati, Department of Pediatrics



**Jason Rosch, Ph.D.**

Inventor, *S. pneumoniae* vaccine  
Associate Member, St. Jude Faculty

## Post IPO Scientific Advisory Board

**Sunetra Gupta, Ph.D.**

Professor, University of Oxford

**C. David Zarley, Ph.D.**

Vaccine Development, Vice  
President., (Retired), Pfizer, Inc.

**John Rice, Ph.D.**

Life Sciences Managing Director,  
CincyTech



# Investment Highlights

*We improve the lives of people through discovery and development of novel, transformational and preventive vaccines*

**Broad and diverse vaccine pipeline:** Novel preclinical vaccine candidates with near-term POC and IND

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

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

**AOM Prevention Candidate:** Targeting *S. pneumoniae* utilizing a proprietary live-attenuated strain with intranasal delivery

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

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

POC: Proof-of-Concept    IND: Investigational New Drug Application.    AOM: acute otitis media

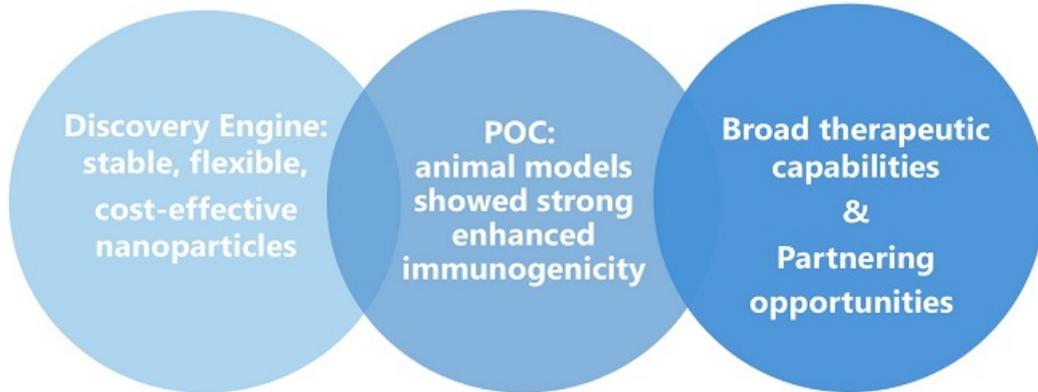
# Next-Generation Novel Vaccine Pipeline

Infectious Disease Program	Candidate	Preclinical	Phase 1	Phase 2	Phase 3	Licensee	*Status
Universal Flu							1H22: pre-clinical POC
H1 pre-pandemic							1H22: start IND enabling studies
S. pneumo induced AOM (intranasal)							1H22: start IND enabling studies
Norovirus / Rotavirus							1H22: pre-clinical POC
Norovirus / Malaria							2H22: start IND enabling studies

\* Pipeline projections are based upon the completion of the initial public offering.

# Our Novel Vaccine Platform<sup>1</sup>

**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**





## Our Vaccine Candidates

# BWV-101: Universal Flu

## BWV-102: H1



*Aiming to eradicate the flu,  
universally, with a smart vaccine  
that targets frequently occurring  
virulent epitopes.*

# Influenza

## Overview<sup>3</sup>

### Worldwide estimates each year:

- **1 billion cases** of influenza infection
- **3-5 million severe cases**
- **290,000-650,000 deaths**

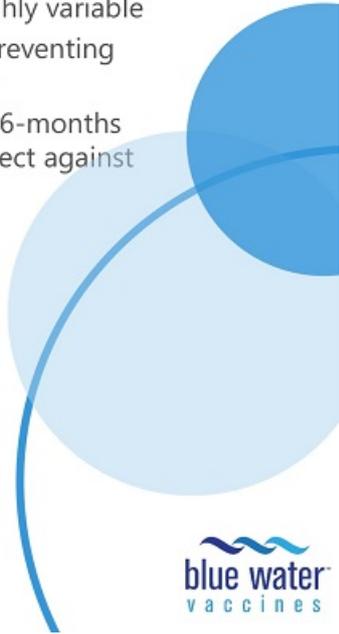
## Economic Impact<sup>4</sup>

- **\$4 billion** is spent annually on influenza vaccines worldwide
- **\$87 billion** estimated lost productivity in the US alone

## Current Treatment limitations<sup>5</sup>

- Target regions of the virus that is highly variable
- Annual flu vaccine effectiveness at preventing disease ranges between 20 and 60%
- Updated annually and reformulated 6-months prior to flu season and may not protect against subsequent strains

***Our mission is grounded in the belief that vaccines are the best way to protect against the flu***



blue water  
vaccines

# Influenza Viruses<sup>6</sup>

Influenza A: epidemic and pandemic

Influenza B: epidemic, slower mutations

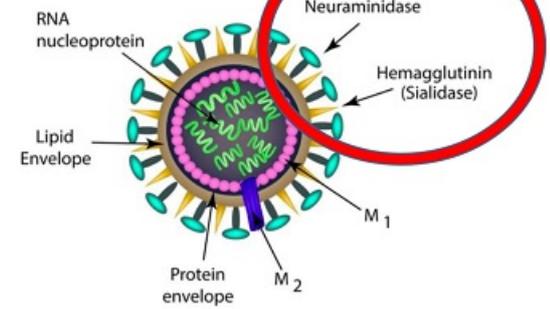
Influenza C: mild, non-pandemic, vaccine not needed

Influenza D: animals only

Subtypes based on two viral proteins:  
H: hemagglutinin (HA)  
N: neuraminidase

Lineages  
B: Victoria  
B: Yamagata

Structure of Influenza virus



Influenza A&B cause most of human illness and the flu season

18 different hemagglutinin subtypes (H1-H18)

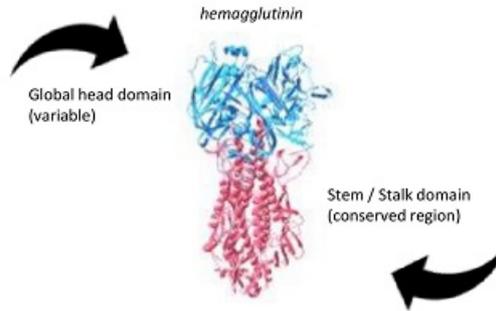
11 different neuraminidase subtypes (N1-N11)

# Our Approach

Current influenza vaccine can be divided into two groups:

Target regions that are highly immunogenic of high variability or evolve frequently.

These vaccines need to be updated regularly and administered annually.



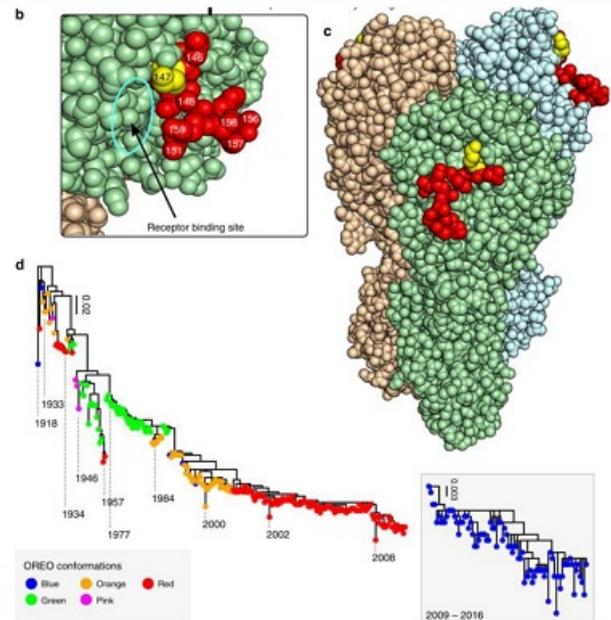
Target regions that are conserved with low immunogenicity.

There is less need for updating these vaccines, but they provide a poor immune response.

**Our vaccine overcomes such issues by targeting regions, or epitopes, of the virus which are of limited variability. These epitopes remain present through the virus mutations.**

**By identifying multiple epitopes of limited variability, it is possible to produce vaccines or a single vaccine to protect against all previous and future H1 flu strains.**

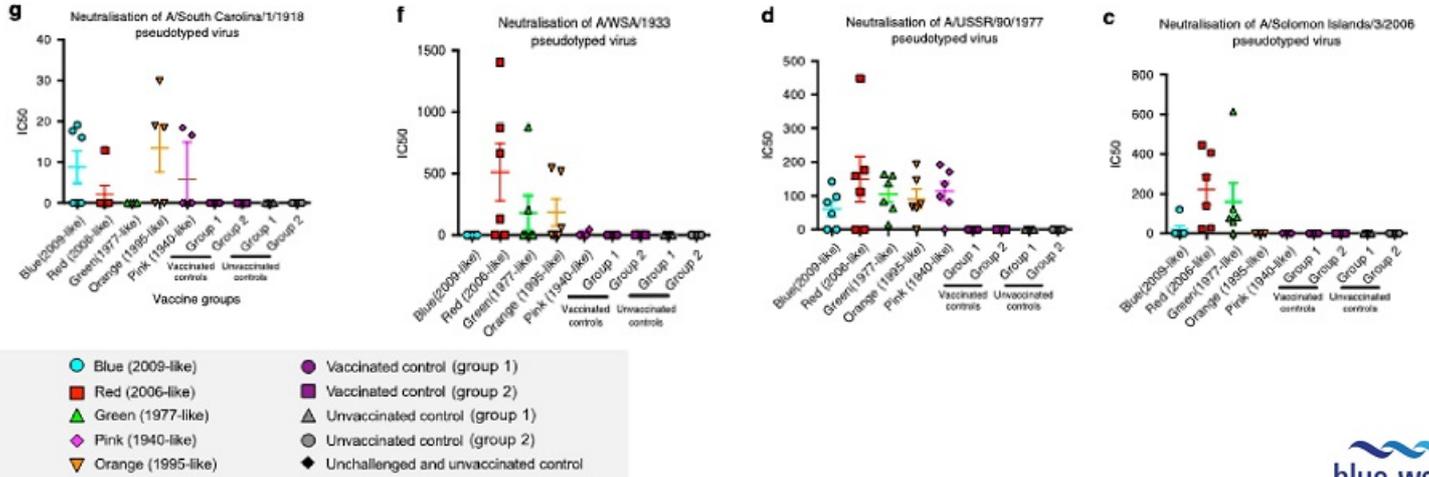
- Antigen/epitope evolution is limited in certain regions of the influenza virus
- ELVs are naturally immunogenic
  - Drive antigenic evolution which could result in a pandemic
  - Cycle between limited number of different conformations
- We licensed IP for cross-protective epitopes for our vaccine candidates:
  - Developed at the University of Oxford by Dr. Sunetra Gupta
  - Mathematical research has pinpointed ELVs that provide immunity to multiple strains
  - Identified ELVs in historical H1, H3 influenza and influenza B strains



# ELV vaccine Proof-of-concept<sup>7</sup>

Vaccination of mice with epitopes from H1N1 influenza viruses circulating in 2006 and 1977 provided protection against a strain that last circulated in 1934

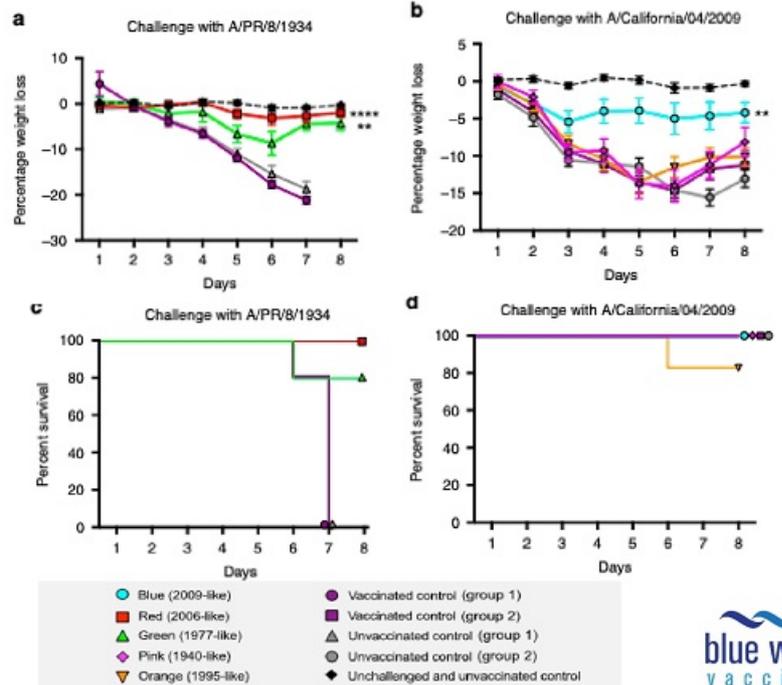
Data demonstrate H1N1 ELVs provide cross-reactive immune response in historical influenza strains



# ELV vaccine Proof-of-concept<sup>7</sup>

## Influenza challenge

- Data in mice models demonstrated that vaccinated mice did not have as severe of a reduction in weight loss compared to the control groups
- Survival curves demonstrated that vaccinated mice were able to produce antibodies to protect against historical flu strains



# Our Influenza Vaccine Program<sup>7</sup>

**Using our proprietary computational approach, we are able to optimize the design of the domains.**

- **BWV-101:**

- Identified naturally immunogenic epitopes for H1, H3 and influenza B.
- Continued discovery and optimization of H3 and Influenza B epitopes
- Exploring S<sub>60</sub> and P<sub>24</sub> Presentation of ELVs.

- **BWV-102:**

- To address potential pandemic zoonotic H1 strains, specifically the G4 EA H1N1 identified by scientists and reported on in June 2020, as the potential next pandemic strain. [2]
- Broad cross-reactive antibodies in other strains such as H10N3 (bird flu), and pandemic strains including H5NX, H7NX, and H9NX.
- Therefore, we foresee the development of H1N1 vaccine as a priority due to its high cross-reactive priorities

**VLP Presentation assessments are targeted for the first half of 2022**

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<sup>17</sup> 7. Thompson et al. Nature Communications. 2018. 9:385 [2]Sun et al. PNAS June 2020

# BWV-201: *S. Pneumoniae*

## induced acute otitis media (AOM)



*Blue Water Vaccines is committed to alleviating pain in children who suffer from *S. pneumoniae* induced middle ear infections.*

# *S. pneumo* induced AOM

## Overview

### Worldwide estimates each year:

- **709 million cases** per year, with 51% occurring in children under 5 years old<sup>8,10</sup>
- By 3 years of age, 80% of children are expected to have at least one episode<sup>8</sup>
- AOM due to *S. pneumoniae* is estimated to be 30-50%<sup>9</sup>

## Impact

- **\$4.3 billion USD** is spent on AOM treatment each year in the U.S. alone<sup>10</sup>

## Current Treatment limitations

- Current treatment for AOM is by antibiotic prescription, with more than 80% of all consultations resulting in a prescription<sup>10</sup>
- Even with introduction of the Prevnar13 in 2010, 26-36% of cases of AOM in U.S. were caused by *S. pneumoniae*<sup>10</sup>

***Current treatments have limited effect on prevention of AOM due to *S. pneumoniae****<sup>10</sup>

# Our Approach

- In-licensed the novel attenuated *S. pneumoniae* strain from St. Jude Children's Research Hospital
- Our BWV-201 vaccine candidate is a live attenuated serotype-independent vaccine
- Long-term preventive intranasal vaccine for *S. pneumoniae* induced acute otitis media (AOM)
  - Potential short-term pain and/or long-term harmful side effects
  - Complications from AOM include sensorineural hearing loss (SNHL)
- Production of vaccine is straightforward
  - Utilizes the entire bacterium with purification and concentration steps only in the downstream process
  - Reduces the time and cost of production significantly compared to the commonly used vaccines

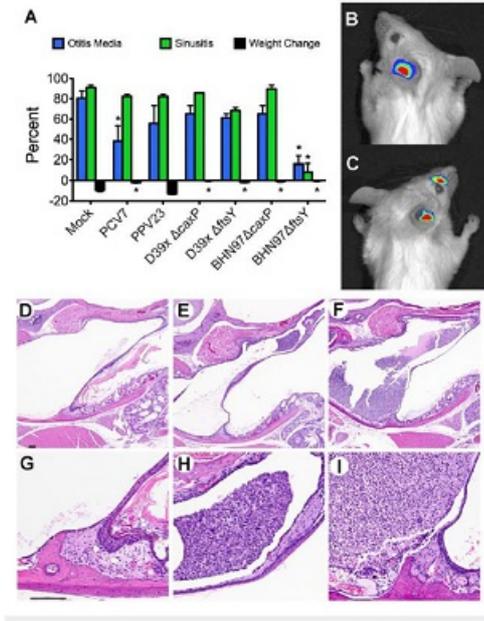
# BWV-201 Proof of Concept<sup>11</sup>

Deletion of *ftsY*, a central component of the signal recognition particle (SRP) pathway show heightened sensitivity to environmental stress and have greatly diminished virulence.

Deletion of *caxP*, a calcium/magnesium transporter, renders host physiological conditions in blood and mucosa toxic to the bacterium.

Vaccines in Study	Serotypes
D39DftsY	2
D39DcaxP	2
BHN97DftsY	19F
BHN97DcaxP	19F
PCV7	4, 6B, 9V, 14, 18C, 19A, 19F & 23 F
PCV13	1, 3, 4, 5, 6B, 7F, 9V, 14, 18C, 19A, 19F & 23 F
PPV23	1, 3, 4, 5, 6B, 7F, 8, 9V, 10A, 11A, 12F, 14, 15, 17A, 18C, 19A, 19F, 20, 22F, 23F & 33 F
Mock	None

# Pre-Clinical Data: Mouse Model<sup>11</sup>



## Vaccine Protection against AOM and sinusitis

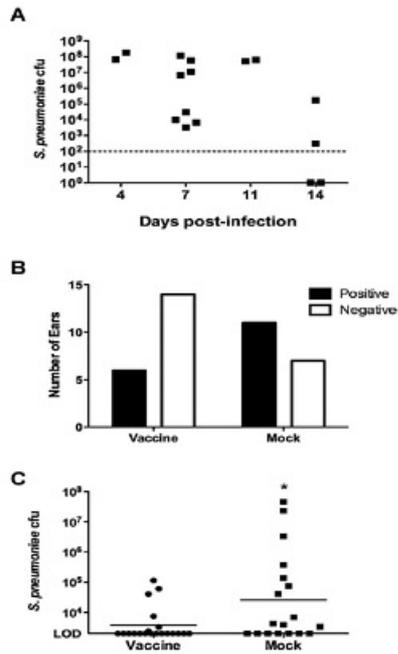
- 25-31 per group, performed at least twice
- Vaccinated with either Mock or live attenuated with deletions on either type 2 or 19 F background.
- Challenged with bioluminescent BMH97X (type 19F), imaged twice daily for AOM and sinusitis

A. The proportion of mice developing infection of ear or sinus by Xenogen imaging PPV23 was used as a negative control

B.,C. Representative pictures from bioluminescent imaging with (B) AOM and (C) both AOM and sinusitis.

D-I. Representative histopathology at 4x (top row) and 40x (bottom row) of (D,G) normal ear, (E,H) mouse with mild AOM and (F,I) marked AOM

# Pre-Clinical Data: Chinchilla Model<sup>11</sup>

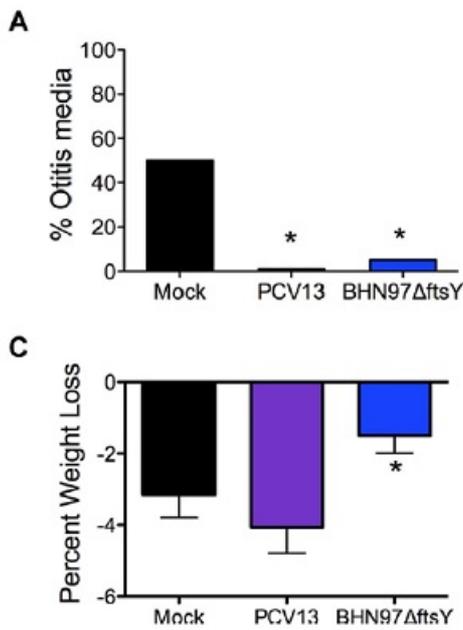


## Vaccine protection in chinchilla model of AOM

A. The BHN97 strain is capable of causing AOM in chinchillas via intranasal administration as observed by recoverable bacterial colony forming units (CFUs) from the middle ear (A) following challenge.

B.,C. Following vaccination, a reduction in the number of culture positive ears in vaccinated group compared to the mock animals was observed (B) as well as significant reduction in recoverable CFUs from middle ear 7 days post challenge (C).

# Pre-Clinical Data<sup>x</sup>: Mouse Model<sup>11</sup>



## Vaccine protection against heterologous challenge

- Mice were mock-vaccinated with PBS (Mock) or vaccinated with PCV13 or a live attenuated vaccine deleted for FtsY on a type 19F background (BNH97ΔftsY).

A. Mice were challenged with a bioluminescent version of *S. pneumoniae* strain BNH54 (type 7F) and assessed by imaging for development of otitis media over 72 h (24 h time point is pictured).

C. Weight loss observed in the animals further supported the observed protection. PCV13 contains type 7F antigen, so this was a homologous challenge for the PCV13 group but a heterologous challenge for the BHN97ΔftsY group.

# BWV 301: Norovirus- Rotavirus

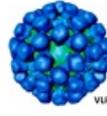


*We aim to mitigate the global abundance of pathogen mediated digestive tract infections via our novel norovirus/rotavirus chimeric vaccine.*



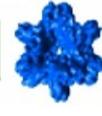
## S-domain

- 60 freely exposed C-termini = S<sub>60</sub> nanoparticle
- Foreign antigens fused to the end of the S domain via flexible linker
- Uniform 60-valent NoV VLPs via an expression system
  - never been produced before.
- S<sub>60</sub> n nanoparticles maintained uniform complexity and size of vaccine particles



## S&P Platform Characteristics

- Unique capsid dual-domain properties: S&P
- Stable, subviral nanoparticles
- Scalable, flexible discovery engine
- Multi-antigen and pathogen capabilities
- Broad therapeutical potential
- Cost-effective and Rapid Production of Novel Vaccines
- *E.coli* expression system



## P-domain

- 24 valent P nanoparticles = P<sub>24</sub>
- Three loops = multi-antigen potential
- Nanoparticles without adjuvant produce innate, humoral, and cellular immunity
- inter-P domain disulfide bonds significantly stabilizes P<sub>24</sub>

# Norovirus-Rotavirus

## Overview

### Worldwide estimates each year:

**Norovirus** is the most common cause of acute gastroenteritis, 700 million cases.<sup>12,14</sup>

- About 200 million cases are seen among children under 5 years old, leading to an estimated 50,000 child deaths every year.<sup>12</sup>

**Rotavirus** causes an estimated 111 million episodes of diarrhea<sup>12</sup>

- 2 million hospitalizations, and 352,000–592,000 deaths in children <5 years of age.<sup>12</sup>

## Economic Impact

- **Norovirus:** \$60.3 billion worldwide each year<sup>13</sup>

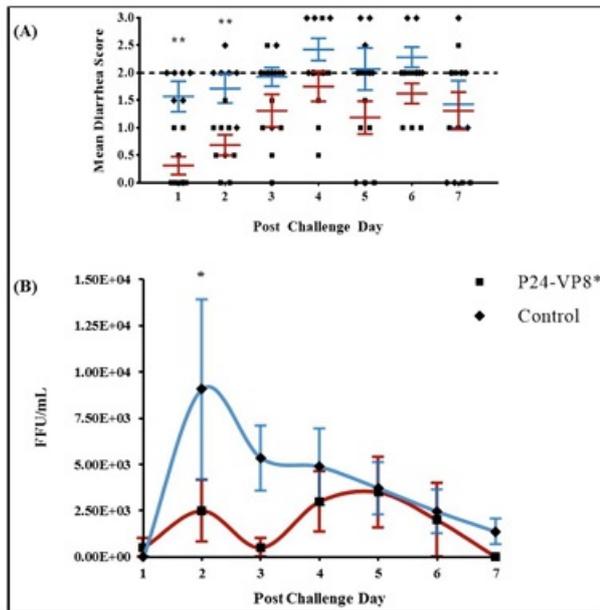
## Current Treatment limitations<sup>12</sup>

- Norovirus: No vaccine is available
- Rotavirus: Current vaccines exist. Two vaccines are authorized for use in infants in the U.S. with a reported efficacy of 85–95%.<sup>15</sup>

*Rotavirus is the most common cause of diarrheal disease among infants and young children<sup>12</sup>*

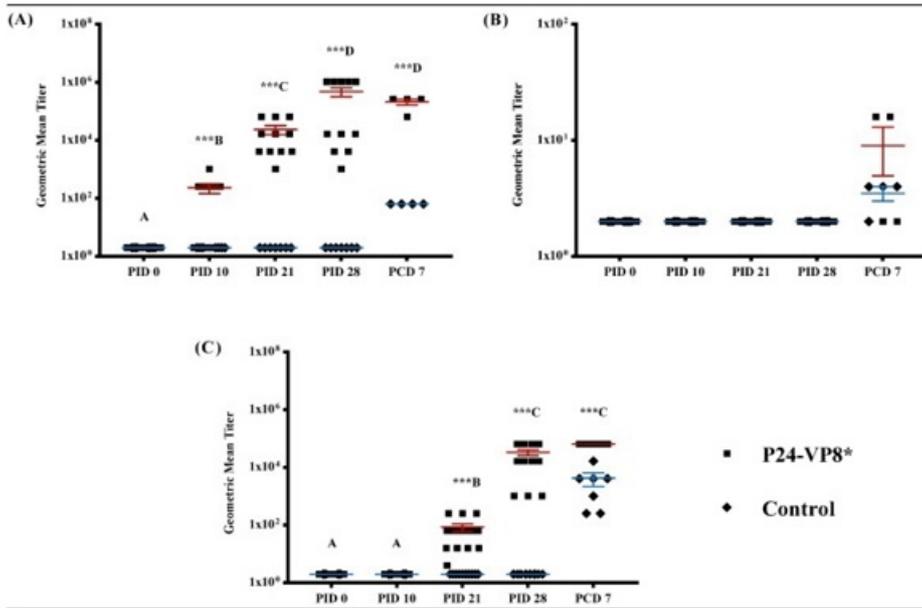
blue water  
vaccines

# Pre-clinical Data: Gnotobiotic Pig Model<sup>16</sup>



P<sub>24</sub>-VP8\* vaccine protected against VirHRV diarrhea and reduced overall viral shedding.

# Pre-clinical Data: Gnotobiotic Pig Model<sup>15</sup>



Vaccine provided neutralizing antibodies in serum collected from gnotobiotic pigs

# BWV 302: Norovirus- Malaria



*We aim to mitigate the global abundance of pathogen mediated digestive tract infections via our novel norovirus/malaria chimeric vaccine.*

# Norovirus-Malaria

## Overview

### Worldwide estimates each year:

Caused by protozoan parasites from the Plasmodium family:

- About 219 million cases were reported in 2019 leading to an estimated 409,000 deaths globally.<sup>17</sup>
- Approximately 67% of the deaths can be attributed to children.<sup>17</sup>

## Economic Impact

- Direct cost of \$12 billion worldwide each year<sup>18</sup>

## Current Treatment limitations<sup>17,19, 20</sup>

- One vaccine currently available for treatment with limited authorization by the EMA in high transmission regions, outside of the of the European Union.
- The two most common treatments are Chloroquine phosphate and Artemisinin-based combination (ACT) therapies

*There is growing concern about resistance to mosquito control pesticides and existing malaria treatment.*<sup>17, 20</sup>

# Pre-clinical Data: Mouse Model<sup>21</sup>

- Vaccination of mice with vaccine candidate P<sub>24</sub> particle presenting the small domain of the CS protein (3D7-PP) and two controls. Mice were immunized three times with the chimeric nanoparticle using aluminum hydroxide as an adjuvant. Sera was collected and evaluated.
- Data demonstrate vaccine candidate produces a higher titer

## Antibody titer after 2<sup>nd</sup> immunization

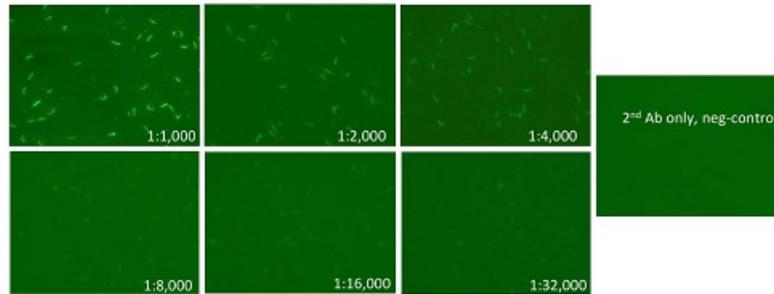
	3D7-PP	3D7-His	3D7-GST
Mouse-1	<b>25600</b>	800	400
Mouse-2	<b>51200</b>	<100	400
Mouse-3	<b>25600</b>	400	400
Mouse-4	<b>25600</b>	<100	800

## Antibody titer after 3<sup>rd</sup> immunization

	3D7-PP	3D7-His	3D7-GST
Mouse-1	<b>201400</b>	25600	12800
Mouse-2	<b>402800</b>	12800	12800
Mouse-3	<b>201400</b>	25600	12800
Mouse-4	<b>402800</b>	12800	12800

# Pre-clinical Data: Mouse Model<sup>21</sup>

## IFA of plasmodium sporozoites (3D7) stained with anti-P24 particle presenting the small domain of the CS protein mouse sera



- The antibodies were also shown to recognize the plasmodium falciparum 3D7 strain using immunofluorescence assays

# Our U.S. IP Portfolio

## S&P Platform<sup>1</sup>:

- US Patent 8,486,421: "Antigen-Norovirus P-Domain Monomers and Dimers, Antigen-Norovirus P-Particle Molecules, and Methods for Their Making and Use"
- US Patent 9,096,644: "Antigen-Norovirus P-Domain Monomers and Dimers, Antigen Norovirus P-Particle Molecules, and Methods for Their Making and Use"
- US Patent 9,562,077: "Protein Complex System For Increased Immunogenicity and Functionality, and Methods Making and Use"
- U. S. patent application no. 16/489,095: "Norovirus S Particle Based Vaccines and Methods of Making and Using Same"
- U.S. provisional application nos. 63/149,742 & 63/162,369: "S60-HA1 pseudovirus nanoparticles as a new influenza vaccine tactic and candidate"

## Influenza<sup>2</sup>:

- US Patent 11,123,422: "Immunogenic composition"
- US patent application no. 17/458,712: "Immunogenic composition"

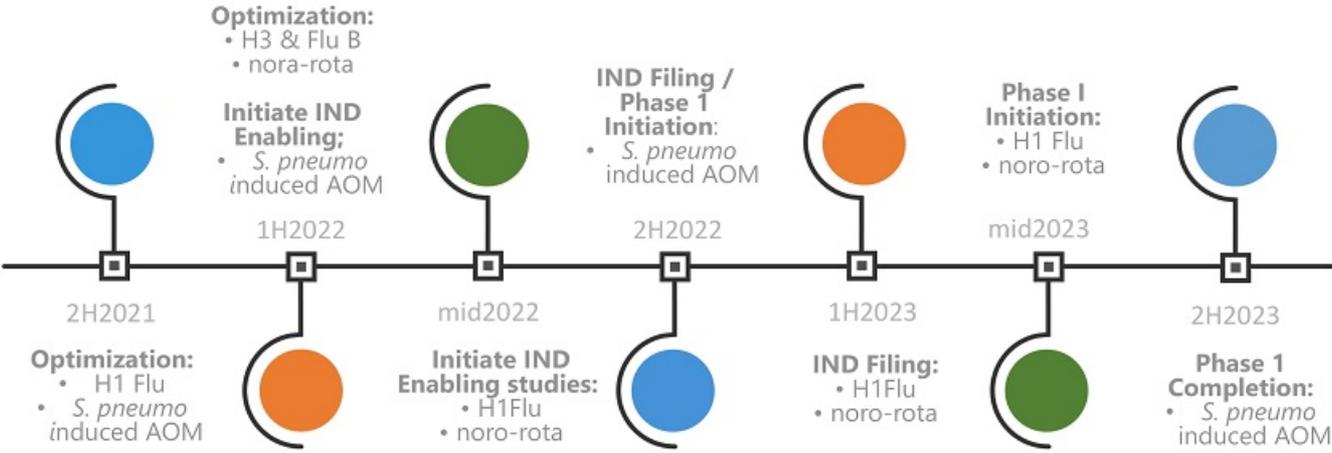
## S. pneumonia<sup>3</sup>:

- US Patent 9,265,819: "Live, attenuated *Streptococcus pneumoniae* strain and vaccine for protection against pneumococcal disease"

## In Process IP<sup>4</sup>:

- OUI project 16867 – Influenza A haemagglutinin antigen Group 2 (H3)
- OUI Project 16870 – Influenza Group B haemagglutinin antigen
- OUI Project 16872 – VLP delivery system for influenza vaccine

# Clinical Development Timeline & Milestones



\* Pipeline projections are based upon the completion of the initial public offering.

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