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): September 12, 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**

(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.

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 September 12, 2022 at the H.C. Wainwright Global Investment Conference in New York, New York.

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	Corporate Presentation, as of September 2022
104	Cover Page Interactive Data File (embedded within the Inline XBRL document).

SIGNATURE

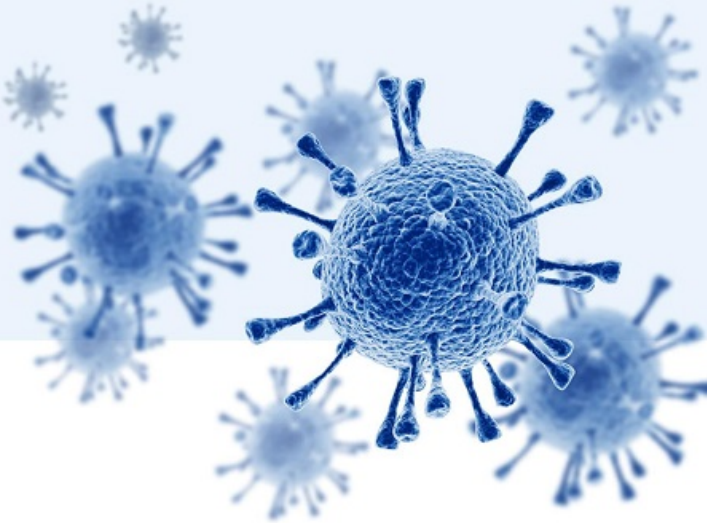
Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

Blue Water Vaccines Inc.

Date: September 12, 2022

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

blue water™
vaccines



September 2022

NASDAQ: BWV

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 of 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, 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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Blue Water Vaccines Overview

Broad and Diverse Vaccine Pipeline: Novel preclinical vaccine candidates targeting key infectious diseases, including acute otitis media (middle ear infections), influenza, norovirus, rotavirus, and malaria

Accomplished Management Team and Board of Directors: Pipeline development and company success driven by management team and board of directors with extensive and diverse industry experience

Esteemed Research Collaborations: Partnerships with renowned researchers, including The University of Oxford, Cincinnati Children's Hospital Medical Center, & St. Jude Children's Research Hospital

Versatile VLP Vaccine Platform: Novel shell and protrusion (S&P) virus-like particle (VLP) platform with potential to develop multiple vaccine candidates, including influenza, monkeypox, norovirus, and rotavirus

Focus on High Unmet Need: Focused development of vaccine candidates targeting high-burden diseases, such as those impacting children and those without efficacious or cost-effective vaccines available

Opportunistic Business Model: Exclusive licenses of assets & platforms and targeted business development efforts contribute to an opportunistic business model promoting company growth and expansion

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Accomplished Management Team and Board of Directors

Led by experienced entrepreneurs with sustained records of successfully leading innovation and commercialization

Joseph Hernandez
Founder, Chairman & CEO

Andrew Skibo
Head of Biologic Operations

Ronald Cobb, Ph.D.
Head of Science and Discovery

Erin Henderson
Chief Business Officer

Jon Garfield
Chief Financial Officer

Board of Directors

Kimberly Murphy
President & CEO, Oragenics, Inc (NYSE: OGEN), Clarus (NASDAQ: CRXT)

James Sapirstein
President & CEO, First Wave Biopharma (NASDAQ: FWBI)

Simon Tarsh
Retired Senior Managing Director for Deloitte Consulting

Michael Venerable
Chief Executive Officer, CincyTech

Renowned Research Partners

Sunetra Gupta, Ph.D.

Co-Inventor, Universal Influenza Vaccine (BWV-101)

Dept. of Zoology, University of Oxford

Xi Jason Jiang, Ph.D.

Co-Inventor, S & P Particle VLP Platform, Norovirus-Rotavirus Vaccine (BWV-301)

Ming Tan, Ph.D.

Co-Inventor, S & P Particle VLP Platform, Norovirus-Rotavirus Vaccine (BWV-301)

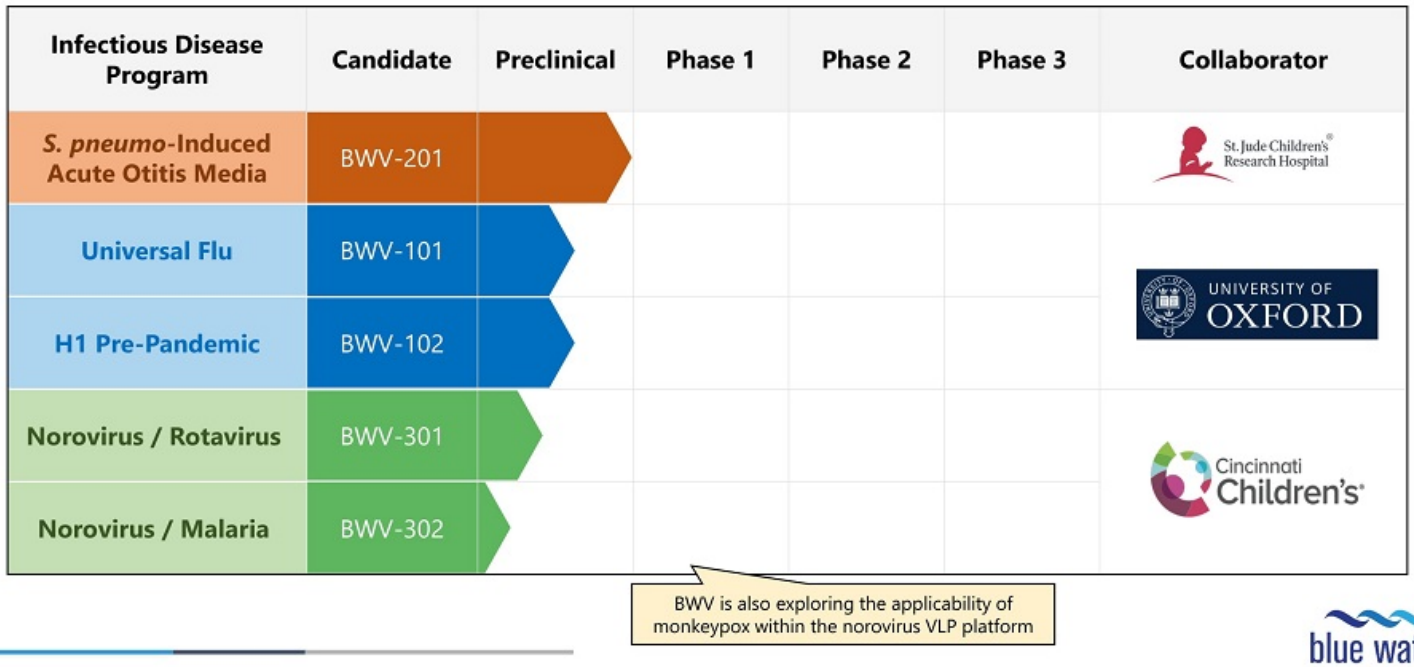
Assistant Professor, University of Cincinnati, Department of Pediatrics

Jason Rosch, Ph.D.

Inventor, S. pneumoniae Vaccine (BWV-201)

Associate Member, St. Jude Faculty

Blue Water Vaccines Pipeline



BWV is also exploring the applicability of monkeypox within the norovirus VLP platform

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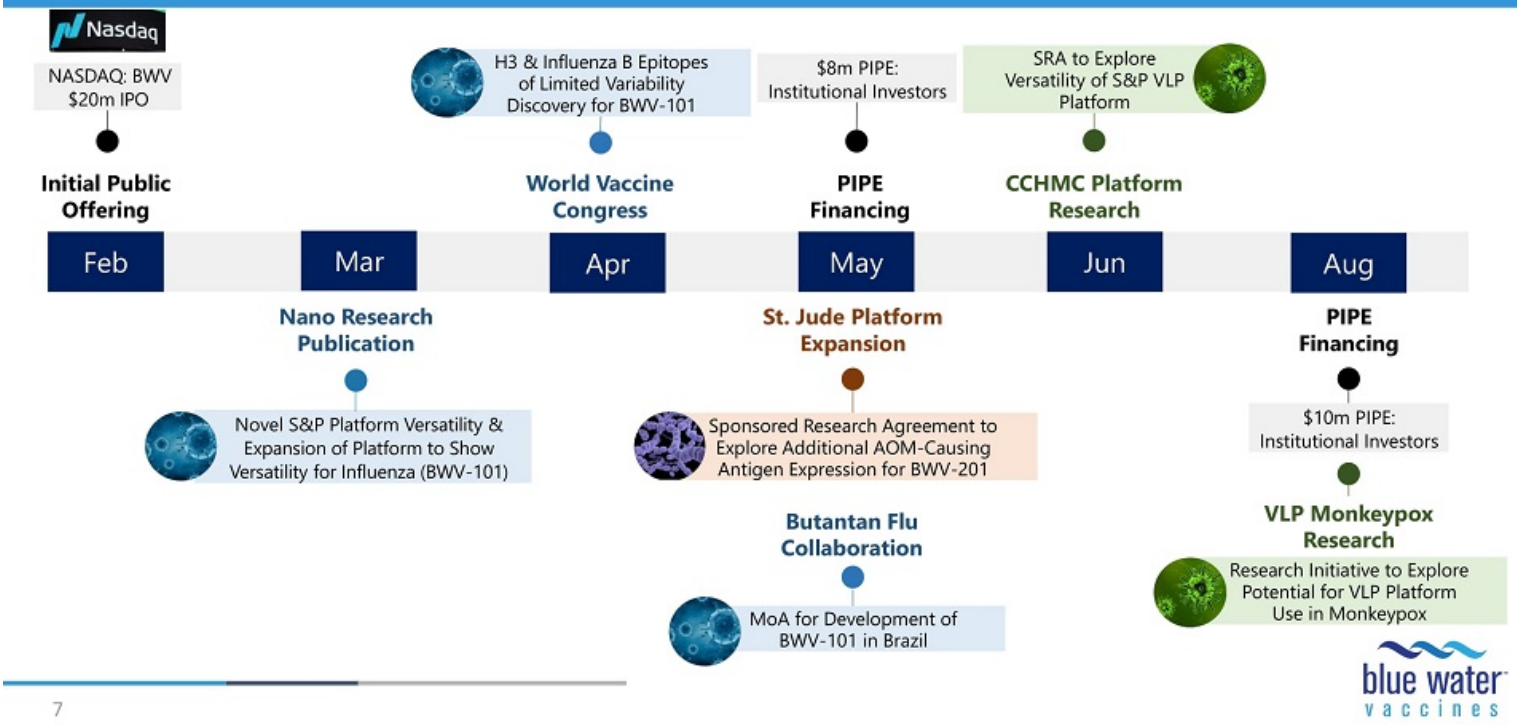
Blue Water Vaccines Recent Execution



Our Vaccine Candidates

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St. Jude Children's Research Hospital

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

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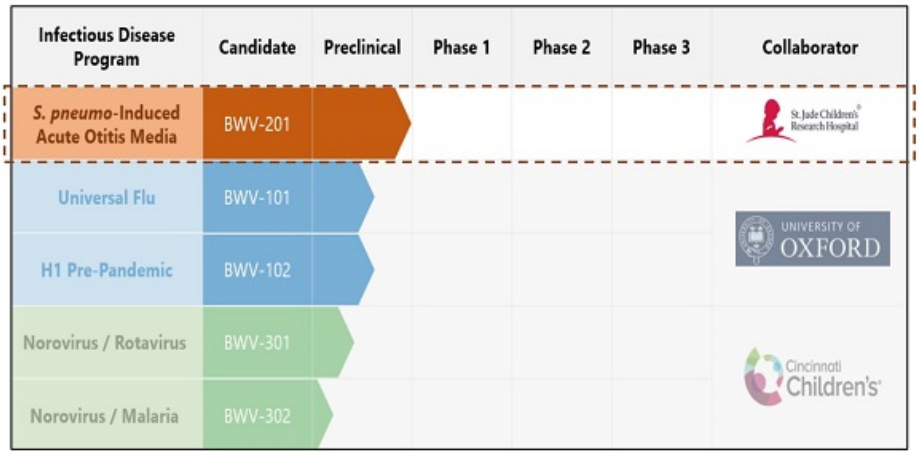
BWV-201 Overview

St. Jude Children's Research Hospital

Blue Water Vaccines Pipeline



BWV-201 Highlights

- **BWV-201** is a live, attenuated, intranasally delivered, modified strain of 19F *Streptococcus pneumoniae*
- Strain is capable of colonization, but not able to cause invasive disease
- Hypothesized to be serotype-independent (e.g., will protect against all AOM-causing strains)
- BWV has an exclusive, global license with St. Jude Children's Research Hospital

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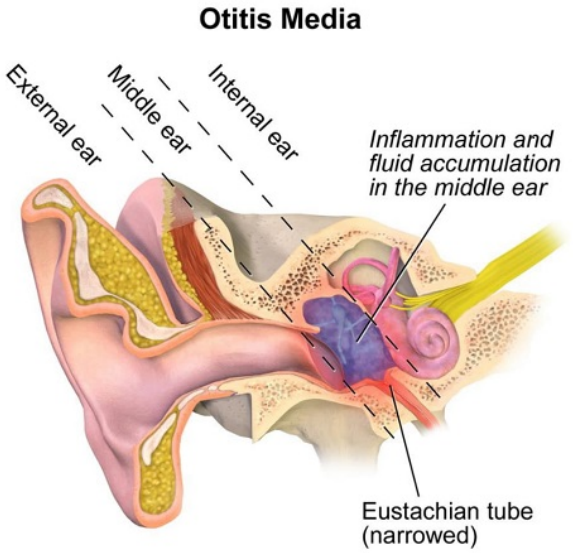
Acute Otitis Media (AOM) Overview

St. Jude Children's Research Hospital



Acute Otitis Media Facts

- **Causes:** Infection can be viral, bacterial, or both
  - Key bacterial pathogens include *Streptococcus pneumoniae,* non-typeable *Haemophilus influenzae,* and *Moraxella catarrhalis*
- **Key Ages Impacted:** Children between 6 – 24mo
  - ~90% of all children will have at least one episode before school age
- **Primary Treatment:** >80% of AOM cases result in antibiotic prescription in the US[1]
- **Complications:** Infection of mastoid bone[2], inflammation of the inner ear[2], and sensorineural hearing loss (SNHL) are all associated with AOM[3]
  - Insertion of tympanostomy tubes for recurrent AOM is the most common ped. procedure in the US, with approximately 667,000 children <15y undergoing the procedure each year[4]

1) Barbieri, E., Donà, D., Cantarutti, A. et al. Antibiotic prescriptions in acute otitis media and pharyngitis in Italian pediatric outpatients. Ital J Pediatr 45, 103 (2019). https://doi.org/10.1186/s13052-019-0696-9
2) Ren Y, Sethi RKV, Stankovic KM. Acute Otitis Media and Associated Complications in United States Emergency Departments. Otol Neurotol. 2018 Sep;39(8):1005-1011. doi: 10.1097/MAO.0000000000001929. PMID: 30113560; PMCID: PMC6097248.
3) Park, J.H., Park, S.J., Kim, Y.H. et al. Sensorineural hearing loss: a complication of acute otitis media in adults. Eur Arch Otorhinolaryngol 271, 1879–1884 (2014). https://doi.org/10.1007/s00405-013-2675-x
4) Spaw M, Camacho M. Tympanostomy Tube. [Updated 2022 May 1]. In: StatPearls [Internet]. Treasure Island (FL): StatPearls Publishing; 2022 Jan-. Available from: https://www.ncbi.nlm.nih.gov/books/NBK565858/

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Acute Otitis Media Market Opportunity

Key Acute Otitis Media Facts & Figures

St. Jude Children's Research Hospital

Small percentage of severe complications from AOM[1]

Tympanostomy tube placement, sensorineural hearing loss & mastoid bone inflammation associated with AOM

2 million emergency department visits[2]

5 million US cases of AOM annually[2]

More than 10 million antibiotic prescriptions[2] (appx. $4.3B US spent annually on treatment[3])

Approximately 30 million annual visits for medical care[3]

Antibiotic Resistance

- With more than 80% of all cases resulting in an antibiotic prescription and possibility of reinfection post treatment[4], antibiotic resistance is of great concern
- One study found the majority of *S. pneumo* strains isolated from children were antibiotic resistant[5]

Current pneumococcal vaccines are serotype-dependent and do not protect against AOM caused by serotypes not included in the vaccine

BWV-201 is serotype-independent and could provide protection against all* S. pneumo *– induced AOM, as well as AOM caused by other bacterial pathogens

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1) Danishyar A, Ashurst JV. Acute Otitis Media. [Updated 2022 Jan 21]. In: StatPearls [Internet]. Treasure Island (FL): StatPearls Publishing; 2022 Jan-. Available from: https://www.ncbi.nlm.nih.gov/books/NBK470332/

2) American Academy of Pediatrics and American Academy of Family Physicians, "Questions and Answers on Acute Otitis Media"

3) Tong S, Amand C, Kieffer A, Kyaw MH. Trends in healthcare utilization and costs associated with acute otitis media in the United States during 2008-2014. BMC

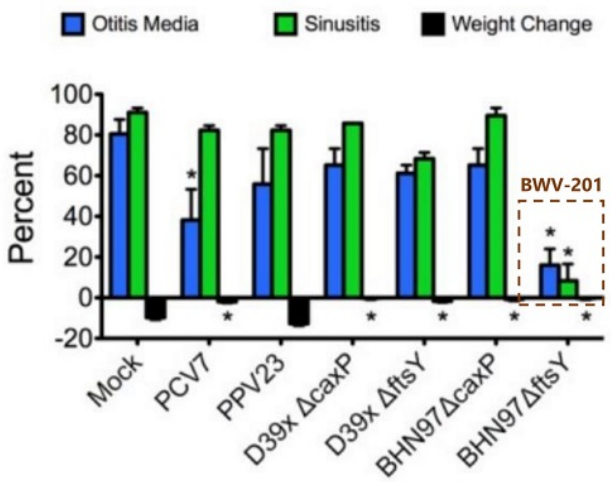
4) Barbieri, E., Donà, D., Cantarutti, A. et al. Antibiotic prescriptions in acute otitis media and pharyngitis in Italian pediatric outpatients. Ital J Pediatr 45, 103 (2019). https://doi.org/10.1186/s13052-019-0696-9

5) Zielnik-Jurkiewicz B, Bielicka A. Antibiotic resistance of Streptococcus pneumoniae in children with acute otitis media treatment failure. Int J Pediatr Otorhinolaryngol. 2015 Dec;79(12):2129-33. doi: 10.1016/j.ijporl.2015.09.030. Epub 2015 Sep 30. PMID: 26454530.

BWV-201 Preclinical Data: Mouse Model[1]

Approach: Mice intranasally vaccinated with BWV-201 (BHN97ΔftsY) or other live, attenuated vaccines vs. placebo and challenged with BHN97 strain

A



NOTE: PCV7 = Prevnar7, PPV23 = Pneumovax23

1. ***Incidence of otitis media and sinusitis was significantly lower in BWV-201 vaccinated mice vs. mock group***
2. ***Other vaccine candidates & PPV23 did not demonstrate significant differences in otitis media or sinusitis vs. mock group***

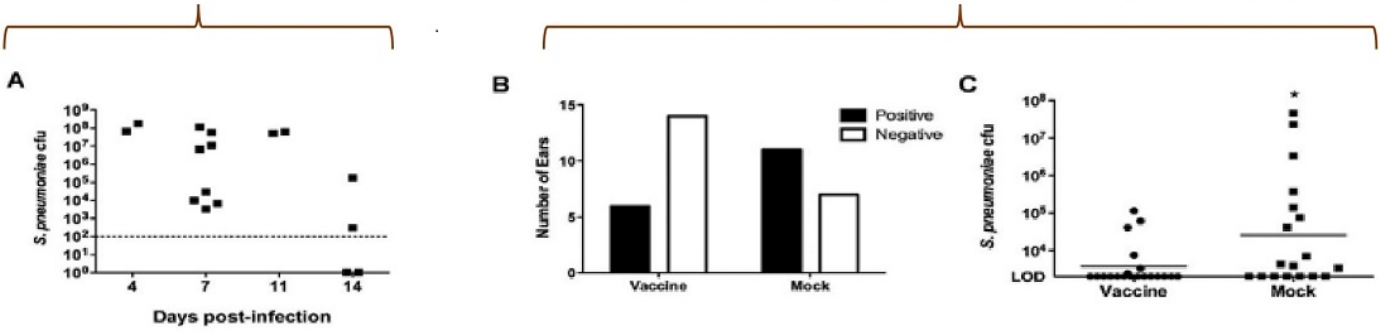
1) Rosch JW, Iverson AR, Humann J, Mann B, Gao G, Vogel P, Mina M, Murrah KA, Perez AC, Edward Swords W, Tuomanen EI, McCullers JA. A live-attenuated pneumococcal vaccine elicits CD4+ T-cell dependent class switching and provides serotype independent protection against acute otitis media. EMBO Mol Med. 2014 Jan;6(1):141-54. doi: 10.1002/emmm.201202150. PMID: 24408968; PMCID: PMC3936495.

BWV-201 Preclinical Data: Chinchilla Model[1]

Approach: Chinchillas intranasally vaccinated with BWV-201 vs. placebo & challenged with BHN97 *S. pneumo* strain to understand immunogenicity and efficacy

Figure A shows BHN97 strain is capable of causing otitis media in chinchillas following intranasal administration

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



1) Rosch JW, Iverson AR, Humann J, Mann B, Gao G, Vogel P, Mina M, Murrah KA, Perez AC, Edward Swords W, Tuomanen EI, McCullers JA. A live-attenuated pneumococcal vaccine elicits CD4+ T-cell dependent class switching and provides serotype independent protection against acute otitis media. EMBO Mol Med. 2014 Jan;6(1):141-54. doi: 10.1002/emmm.201202150. PMID: 24408968; PMCID: PMC3936495.

Sponsored Research Agreement Expansion

St. Jude Children's Research Hospital

Validation of Optimized Live Attenuated Pneumococcal Vaccines

BWV-201 Platform Hypothesis

Express antigens from additional AOM-causing pathogens (e.g., non-typeable Haemophilus influenzae & Moraxella catarrhalis) on BWV-201 surface

Research Agreement Development

BWV & St. Jude extended partnership through Sponsored Research Agreement

Research Execution & Platform Viability

Execute additional expression & test efficacy through animal immunogenicity modeling

☑ ***Sponsored Research Agreement Expansion Signed May 11, 2022***

Results Pending, Provisional Patent Filed

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UNIVERSITY OF OXFORD

BWV-101: Universal Influenza

BWV-102: H1 Pre-Pandemic

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

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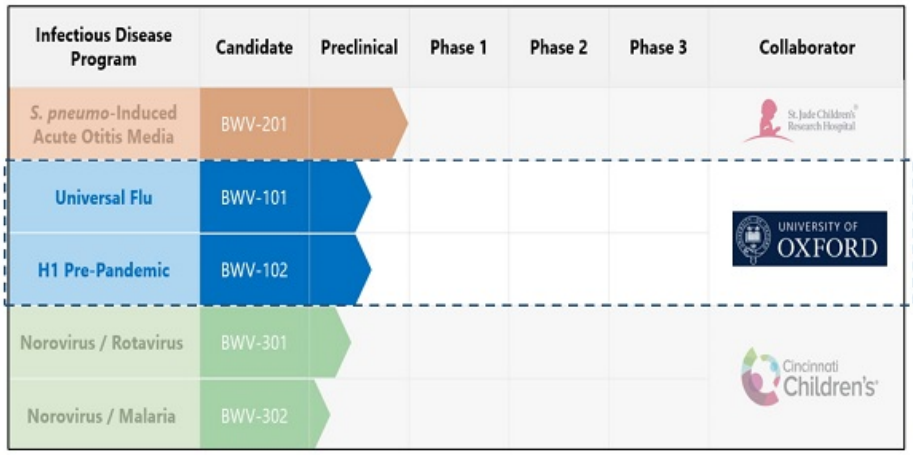
BWV-101 & BWV-102 Overview

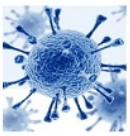
Blue Water Vaccines Pipeline



BWV Influenza Program Highlights

- **BWV-101** is a universal influenza candidate with hypothesized protection against H1, H3, and Flu B strains
- **BWV-102** is a standalone H1, pre-pandemic, influenza vaccine candidate
- Development of both candidates is based on **epitopes of limited variability** discovered through mathematical modeling at The University of Oxford
- BWV holds a global, exclusive license for epitopes of limited variability

Influenza Market Opportunity



Influenza Disease Burden

- **1 billion influenza infections globally** and between **290,000 – 650,000 deaths** each year[1]
- In the US alone, there are about **30 million cases** each year and **30,000 – 50,000 related deaths**[2]
- The total annual economic burden for influenza in the US is about **$87 billion**[3]
- **Influenza A and B** cause most of human illness and the flu season

Current Vaccine Shortcomings

- × Vaccines need to be **manufactured in chicken eggs** which increases time and cost
- × Yearly **reformulations rely on predictions** as to which strains will be dominant that flu season
- × Current annual flu vaccine **effectiveness ranges from 19% – 50%** due to strain variations[4]
- × Given strain evolution, individuals need to **receive shots each year** to provide any sort of protection

With 193.8 million flu shots given in the 2020 – 2021 season[5] and an average CDC cost of $14.68 per adult dose[6], about $2.8 billion was spent on flu shots in the US alone from 2020 - 2021

1) World Health Organization, Global Influenza Programme, "Burden of Disease"
2) Centers for Disease Control and Prevention, "Frequently Asked Questions about Estimated Flu Burden"
3) Molinari NA, Ortega-Sanchez IR, Messonnier ML, Thompson WW, Wortley PM, Weintraub E, Bridges CB. The annual impact of seasonal influenza in the US: measuring disease burden and costs. Vaccine. 2007 Jun 28;25(27):5086-96. doi: 10.1016/j.vaccine.2007.03.046. Epub 2007 Apr 20. PMID: 17544181.
4) Centers for Disease Control and Prevention, "CDC Seasonal Flu Vaccine Effectiveness Studies"
5) Centers for Disease Control and Prevention, "Historical Reference of Seasonal Influenza Vaccine Doses Distributed"
6) Centers for Disease Control and Prevention, "CDC Vaccine Price List, July 1, 2022"

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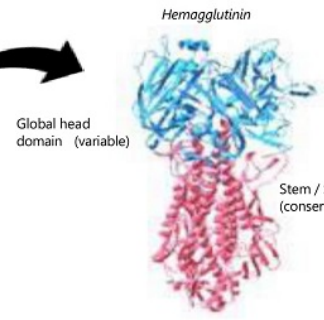
Epitopes of Limited Variability Overview

Current influenza vaccines can be divided into two groups:

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

   These vaccines need to be updated regularly and administered annually.



2. Target regions that are conserved with low immunogenicity.

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

BWV Approach

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.

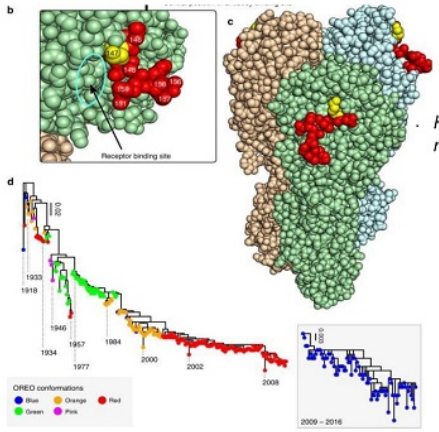
By identifying multiple epitopes of limited variability, it is possible to produce vaccines or a single vaccine to protect against all previous and future H1 flu strains.

1) Thompson, C.P., Lourenço, J., Walters, A.A. *et al.* A naturally protective epitope of limited variability as an influenza vaccine target. *Nat Commun* **9**, 3859 (2018). https://doi.org/10.1038/s41467-018-06228-8

Epitopes of Limited Variability Overview

Epitopes of Limited Variability Discovery & Plan

- **Oxford Discovery:** Antigen/epitope evolution is limited in certain regions of the influenza virus, while previous thought was high evolution within the entire molecule
- **Epitopes of Limited Variability Immunogenicity:** ELVs are naturally immunogenic based on Oxford research
  - ELVs cycle between limited number of different conformations and represent optimal vaccine targets
- **BWV License & Approach:** 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 to combine into a single, universal influenza vaccine candidate



Oxford mathematical modeling showing certain epitopes (named "OREO") remain constant over time

1) Thompson, C.P., Lourenço, J., Walters, A.A. *et al.* A naturally protective epitope of limited variability as an influenza vaccine target. *Nat Commun* **9**, 3859 (2018). https://doi.org/10.1038/s41467-018-06228-8

BWV's Epitopes of Limited Variability Targets

Identified Epitopes of Limited Variability

Influenza A H1N1
"OREO"

One epitope with 5 variants, currently generating additional optimization data between variants

Influenza A H3N2
"INDY", "MAIZ"

Two epitopes with either 4 or 6 variants, currently generating additional neutralization data

Influenza B (Yamagata & Victoria Strains)
"TATI"

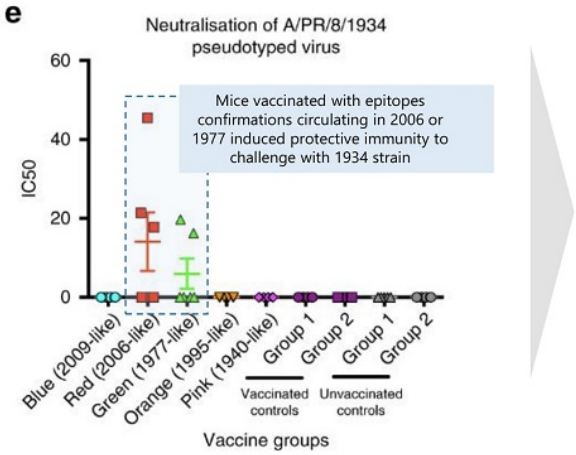
One epitope with 7 variants, currently generating additional neutralization data

BWV-102 is a standalone, H1 pe-pandemic influenza vaccine using OREO epitopes

BWV-101 will include selected epitopes from H1, H3, and Influenza B to create a universal influenza vaccine candidate

Epitopes of Limited Variability Proof of Concept

Approach: Mice were vaccinated with identified influenza A H1 epitope confirmations and challenged with historical influenza A strains to confirm cross-reactivity and epitope conservation across strains



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

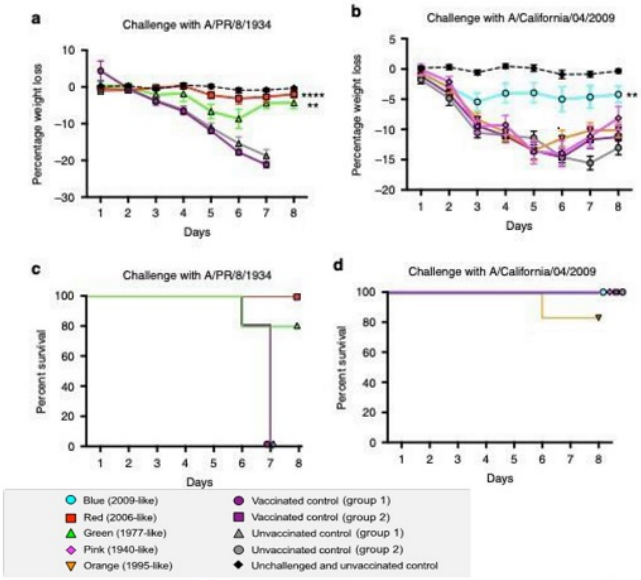
BWV-101 and BWV-102 contain epitopes of limited variability to provide broad protection against most historic and future influenza strains

NOTE: Additional figures showing cross-reactivity to other historical strains have been demonstrated[1]

1) Thompson, C.P., Lourenço, J., Walters, A.A. *et al.* A naturally protective epitope of limited variability as an influenza vaccine target. *Nat Commun* **9**, 3859 (2018). https://doi.org/10.1038/s41467-018-06228-8

Epitopes of Limited Variability Proof of Concept

Approach: In addition to cross-reactivity, understand if antibodies directed against these epitopes confer protective immunity against historic strains



Vaccination with the 2006-like and 1977-like OREO epitope confirmations conferred immunity to challenge with a strain that last circulated in 1934

1) Thompson, C.P., Lourenço, J., Walters, A.A. *et al.* A naturally protective epitope of limited variability as an influenza vaccine target. *Nat Commun* **9**, 3859 (2018). https://doi.org/10.1038/s41467-018-06228-8

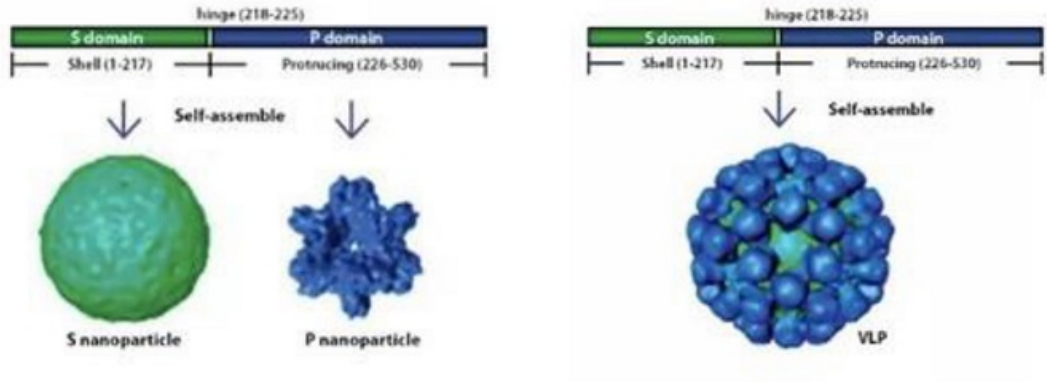
S&P Nanoparticle VLP Platform

BWV-301: Norovirus – Rotavirus

We aim to create a novel, versatile vaccine platform applicable to multiple infectious diseases for transformative vaccines

Versatile Nanoparticle Virus-Like Particle Platform

Shell and Protrusion Particle Characteristics



- ✓ **Comprised of 2 nanoparticles:** S60 and P24 with norovirus backbone
- ✓ Ability to **present additional antigens** on either particle from multiple infectious diseases
- ✓ **Broad therapeutic capabilities** and a **cost-effective** vaccine development platform
- ✓ **Proof-of-concept in animal models** showing strong & enhanced immunogenicity

BWV-301 Norovirus-Rotavirus Overview

Norovirus & Rotavirus Impact

- **Norovirus** is the most common cause of acute gastroenteritis, with about 700 million cases each year
  - About 200 million cases are in children under 5 years old, leading to an estimated 50,000 child deaths each year[1]
  - Estimated $60.3 billion spent on treatment each year[2]
- **Rotavirus** causes an estimated 111 million cases of gastroenteritis each year
  - 2 million hospitalizations are reported each year, along with 122,000 – 215,000 deaths[3]

Vaccination Needs

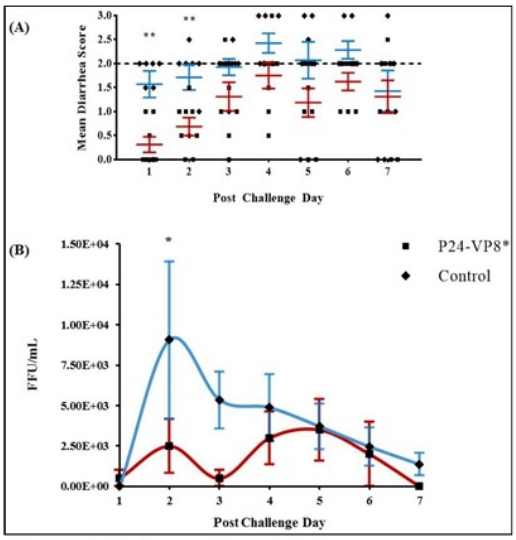
There are no commercially-available norovirus vaccines despite high disease burden in developed and developing countries

While there are several available rotavirus vaccines, efficacy in low-income countries is lower & more efficacious vaccines are needed

1) Centers for Disease Control and Prevention, "Norovirus Worldwide"
2) Tan M. Norovirus Vaccines: Current Clinical Development and Challenges. Pathogens. 2021 Dec 19;10(12):1641. doi: 10.3390/pathogens10121641. PMID: 34959596; PMCID: PMC8709042.
3) World Health Organization, "Rotavirus Vaccines: WHO position paper – July 2021"

BWV-301 Preclinical Data: Gnotobiotic Pig Model[1]

Approach: Assess the immunogenicity and protective efficacy of the P24-VP8* nanoparticle in gnotobiotic pig model of human rotavirus infection and disease using mean diarrheal score and quantified viral shedding



NOTE: Red indicates range for vaccinated animals, blue indicates ranges for unvaccinated

Vaccinated animals (red) showed significantly reduced duration of diarrhea, lower mean diarrhea scores, and lower cumulative fecal consistency scores

Vaccinated animals (red) showed significantly less overall virus shedding compared to unvaccinated (blue), indicating neutralization of the virus

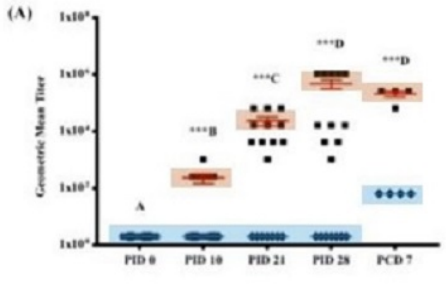
1) Ramesh A, Mao J, Lei S, Twitchell E, Shiraz A, Jiang X, Tan M, Yuan AL. Parenterally Administered P24-VP8* Nanoparticle Vaccine Conferred Strong Protection against Rotavirus Diarrhea and Virus Shedding in Gnotobiotic Pigs. Vaccines (Basel). 2019 Nov 6;7(4):177. doi: 10.3390/vaccines7040177. PMID: 31698824; PMCID: PMC6963946.

BWV-301 Preclinical Data: Gnotobiotic Pig Model[1]

Approach: Assess the immunogenicity and protective efficacy of the P24-VP8* nanoparticle in gnotobiotic pig model by measuring antibody titers & immune response indicators

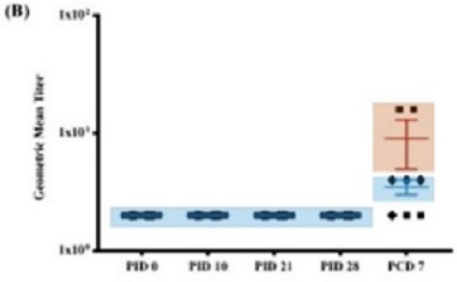
- P24-VP8*
- Control

Serum IgG Levels



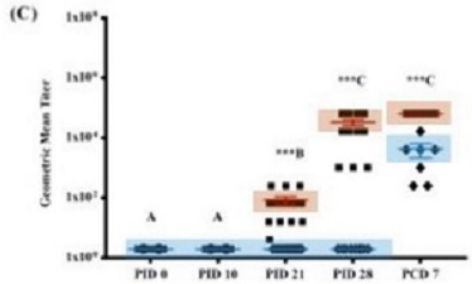
P24-VP8*-specific IgG antibody titers were significantly higher in vaccinated pigs vs. control

Serum IgA Levels



Serum IgA titers only detectable after challenge at PCD 7

HRV Neutralizing Antibody Levels



HRV neutralizing antibodies were detected in serum of vaccinated pigs vs. control pigs only show detection post-challenge

NOTE: Red indicates range for vaccinated animals, blue indicates ranges for unvaccinated

HRV = Human Rotavirus

1) Ramesh A, Mao J, Lei S, Twitchell E, Shiraz A, Jiang X, Tan M, Yuan AL. Parenterally Administered P24-VP8* Nanoparticle Vaccine Conferred Strong Protection against Rotavirus Diarrhea and Virus Shedding in Gnotobiotic Pigs. Vaccines (Basel). 2019 Nov 6;7(4):177. doi: 10.3390/vaccines7040177. PMID: 31698824; PMCID: PMC6963946.

BWV-301 Preclinical Data: Mouse Model

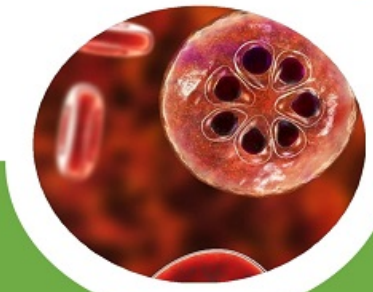
Approach: Vaccination of mice with vaccine candidate P_{24} particle presenting the small domain of the CS protein (3D7- PP) and two controls to demonstrate immunogenicity of vaccine candidate

	Antibody Titer After 2nd Immunization			Antibody Titer After 3rd Immunization		
	3D7-PP	3D7-His	3D7-GST	3D7-PP	3D7-His	3D7-GST
Mouse 1	**25600**	800	400	**201400**	25600	12800
Mouse 2	**51200**	<100	400	**402800**	12800	12800
Mouse 3	**25600**	400	400	**201400**	25600	12800
Mouse 4	**25600**	<100	800	**402800**	12800	12800

Vaccine candidate produces higher titer of antibodies, indicating immune response and potential immunogenicity

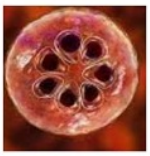
S&P Nanoparticle VLP Platform

BWV-302: Norovirus – Malaria



We aim to create a novel, versatile vaccine platform applicable to multiple infectious diseases for transformative vaccines

Malaria Overview



Malaria Overview & Impact

- Caused by protozoan parasites from the **Plasmodium family**
- About **219 million cases** reported in 2019 leading to an estimated **409,000 deaths** globally[1]
- Approximately **67% of deaths can be attributed to children**[1]
- Direct costs of approximately **$12 billion worldwide** each year[2]

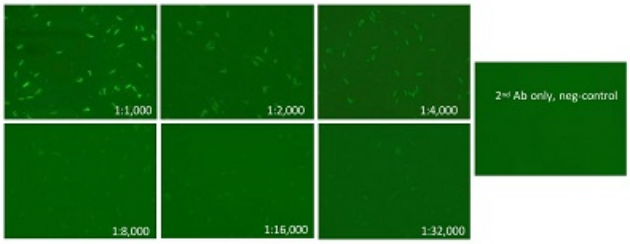
Treatment Limitations

- × One vaccine is available for treatment with limited authorization by the EMA in high transmission regions[3]
- × Two most common treatments are Chloroquine phosphate & Artemisinin-based combination (ACT) therapies[4]
- × Growing concern about resistance to mosquito control pesticides and existing malaria treatment[5]

1) World Health Organization, "Malaria – Key Facts, 26 July 2022"
2) Centers for Disease Control and Prevention, "Malaria's Impact Worldwide"
3) World Health Organization, "WHO recommends groundbreaking malaria vaccine for children at risk", 6 October 2021
4) Mayo Clinic, "Malaria Diagnosis and Treatment"
5) Uwimana, A., Legrand, E., Stokes, B.H. et al. Emergence and clonal expansion of in vitro artemisinin-resistant Plasmodium falciparum kelch13 R561H mutant parasites in Rwanda. Nat Med 26, 1602–1608 (2020). https://doi.org/10.1038/s41591-020-1005-2

BWV-302 Overview and Hypothesis

Approach: Incorporate sequences from plasmodium sporozoites into P24 VLP and test VLP viability and test mouse sera for reactivity using immunofluorescence assays

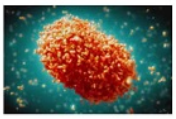


IFA of plasmodium sporozoites (3D7) stained with anti-P24 particle presenting the small domain of the CS protein mouse sera

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

Plasmodium sporozoites that cause infection can be attached to the P-particle in the S&P platform (detected using immunofluorescence) and may represent a novel malaria vaccine candidate

Monkeypox Market & Vaccine Exploration



Monkeypox Overview & Impact

- Monkeypox virus is part of the same family of viruses as variola virus, the virus that causes smallpox[1]
- Symptoms are similar to that of smallpox, but milder, and monkeypox is rarely fatal[1]
- First human case recorded in 1970, with infrequent cases in several central and western African countries[1]
- 2 available monkeypox vaccines:
  - **JYNNEOS vaccine:** Live, attenuated, non-replicating smallpox and monkeypox vaccine given in a 2-dose series with doses 28 days apart[2]
  - **ACAM2000 vaccine:** Live vaccinia virus administered via bifurcated needle[2]

Monkeypox Vaccine Opportunity

- ✓ Provide alternative vaccine options to meet global need
- ✓ Develop non-live vaccines that are still capable of eliciting an immune response

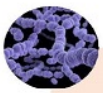
BWV Monkeypox Approach

- ✓ **Utilize VLP platform** licensed from Cincinnati Children's to present monkeypox and/or smallpox antigens within the norovirus S & P particles
- ✓ Once constructs are generated, BWV will **assess vaccine's ability to elicit an immune response** in an animal model
- ✓ Once immunogenicity is assessed, BWV will **assess the scalability and manufacturability** of the vaccine

1) CDC, "About Monkeypox", July 22, 2022
2) CDC, "Monkeypox Vaccines", August 30, 2022

Summary and Recent Milestones

Vaccine Candidate Developments



BWV-201: *S. pneumoniae – induced AOM*

- **May 2022:** Expanded St. Jude Sponsored Research Agreement to explore presentation of additional AOM-causing pathogens into BWV-201

BWV-101 & 102: *Influenza*

- **April 2022:** Presented discovery of H3 and Flu B epitopes of limited variability at World Vaccine Congress
- **May 2022:** Announced collaboration with Instituto Butantan for development of BWV-101 in Brazil
- **May 2022:** Expanded Oxford Sponsored Research Agreement to continue funding for influenza research

BWV-301 & 302: VLP S&P Platform

- **July 2022:** Signed Sponsored Research Agreement with Cincinnati Children's for VLP Platform Exploration & Development
- **August 2022:** Announced exploration of VLP platform applicability to develop a novel monkeypox vaccine candidate

Corporate Developments

- **February 2022:** Completed $20M Initial Public Offering (NASDAQ: BVW)
- **May 2022:** Completed $8M Private Placement with institutional investors
- **August 2022:** Completed $10M Private Placement with institutional investors
- **Cash Runway:** IPO and subsequent private placements have secured cash runway into 2024

blue water vaccines

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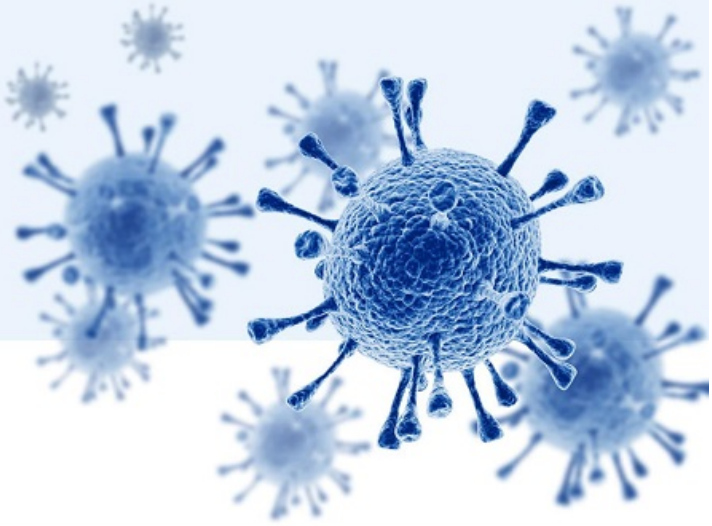
vaccines



Thank you!

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