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): December 1, 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

Emerging growth company ☒

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

Item 7.01 Regulation FD Disclosure.

On December 1, 2022, Blue Water Vaccines, Inc. (the "Company") issued a press release announcing that on December 1, 2022 the Company will present an update on novel, live attenuated, intranasally delivered *Streptococcus pneumoniae* vaccine to prevent acute otitis media, pneumococcal pneumonia, and invasive pneumococcal disease at the World Vaccine and Immunotherapy Congress West Coast 2022 in San Diego, California (the "World Congress").

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

Attached as Exhibit 99.2 to this Current Report is the form of presentation that the Company intends to present at the World Congress on December 1, 2022.

The foregoing (including Exhibit 99.1 and Exhibit 99.2) 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	Press Release dated December 1, 2022
99.2	Presentation dated December 1, 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: December 1, 2022

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

Exhibit 99.1

Blue Water Vaccines to Present Update on Novel, Live Attenuated, Intranasally Delivered *Streptococcus pneumoniae* Vaccine to Prevent Acute Otitis Media, Pneumococcal Pneumonia, and Invasive Pneumococcal Disease at the World Vaccine & Immunotherapy Congress West Coast 2022

CINCINNATI, OH, December 1, 2022 -- Blue Water Vaccines Inc. ("BWV" or "Blue Water Vaccines" or the "Company"), today announced that Ali Fattom, Ph.D., will present at the World Vaccine & Immunotherapy Congress West Coast 2022 in San Diego, California on Thursday, December 1, 2022. Dr. Fattom will present an overview and current progress of BWV-201, a live attenuated, intranasally delivered, serotype independent *Streptococcus pneumoniae* vaccine candidate for the prevention of acute otitis media ("AOM"), pneumococcal pneumonia, and invasive pneumococcal disease.

Session details are as follows:

Date:	Thursday, December 1, 2022
Time:	1:55 p.m. Eastern Daylight Time (EDT)
Title:	A Combinatorial Live Attenuated Vaccine Strategy Against Pneumonia and Otitis Media
BWV Participant:	Ali Fattom, Ph.D.

"This program has made significant clinical development progress this year, and we are very excited to showcase our technology at such a prestigious event," said Joseph Hernandez, Chairman and Chief Executive Officer of Blue Water Vaccines. "Although our primary targets of this vaccine remain AOM and pneumococcal pneumonia, data from the original publication for this vaccine suggests that BWV-201 may also protect against invasive pneumococcal disease. We look forward to sharing our strategy with all colleagues in attendance and further advancing this program into clinical trials."

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, St. Jude Children's Hospital, and The University of Texas Health San Antonio. The Company is developing a universal flu vaccine that will provide protection from all virulent strains in addition to licensing a novel norovirus (NoV) S&P nanoparticle versatile virus-like particle (VLP) vaccine platform from Cincinnati Children's to develop vaccines for multiple infectious diseases, including norovirus/rotavirus and malaria, among others. Additionally, Blue Water Vaccines is developing a *Streptococcus pneumoniae* (*pneumococcus*) vaccine candidate, designed to specifically prevent the highly infectious middle ear infections, known as Acute Otitis Media (AOM), in children. The Company is also developing a *Chlamydia* vaccine candidate with UT Health San Antonio to prevent infection and reduce the need for antibiotic treatment associated with contracting *Chlamydia* disease. 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; 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, filed with the Securities and Exchange Commission (the "SEC") on August 29, 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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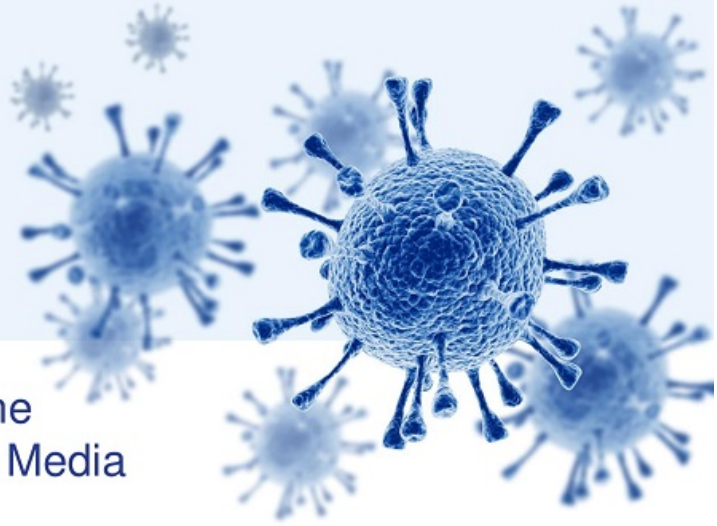
vaccines



A Combinatorial Live Attenuated Vaccine Strategy Against Pneumonia and Otitis Media

Ali Fattom, Brian Price, Ron Cobb, and
Jason Rosch*
Bluewater Vaccines Inc
December 1, 2022

NASDAQ: BWV

*Department of Infectious Diseases
St. Jude Children's Research Hospital, Memphis, TN

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 Registration Statement on Form S-1, filed with the Securities and Exchange Commission (the "SEC") on August 29, 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.

Pneumococcal Vaccines: Success and Limitations

Problem: Pneumococcus causes both mucosal diseases (e.g., acute otitis media, sinusitis, pneumonia) as well as invasive infection (bacteremia, sepsis, and meningitis) predominantly in children and elderly

Success

- ✓ Introduction of the highly efficacious polysaccharide-conjugate vaccines (e.g., Prevnar series, Synflorix, etc.) reduced invasive pneumococcal infections rapidly and dramatically following introduction across all age groups

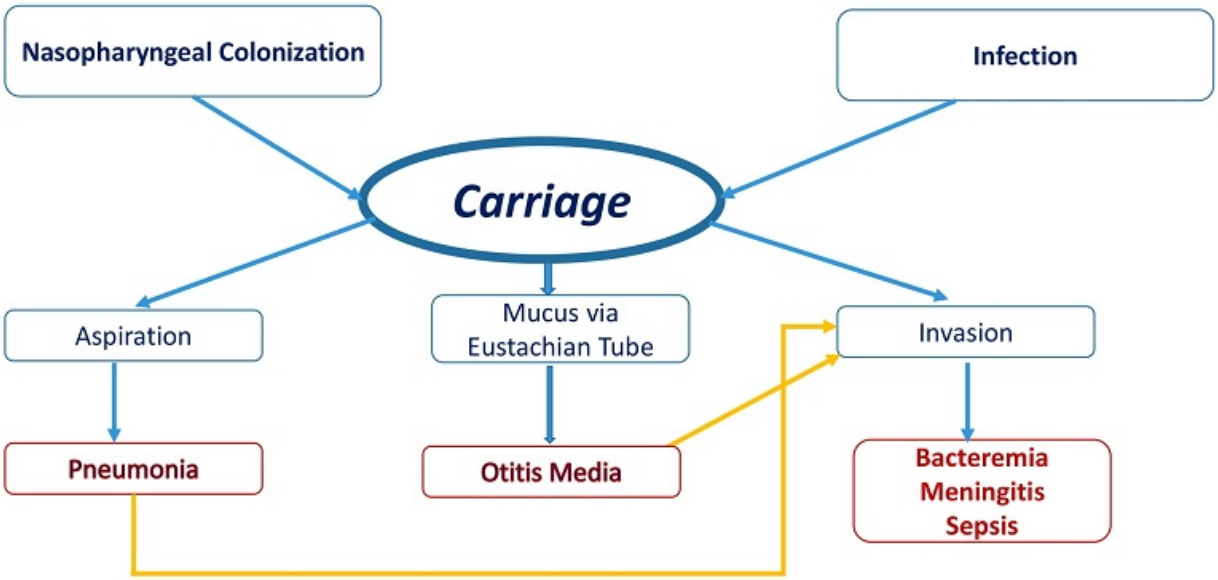
Limitations

- × Protection is serotype specific
- × Efficacy was almost exclusive to invasive diseases including bacteremia, sepsis, and meningitis
- × Emergence of non-vaccine type in the community
- × Cost and availability in resource limited setting
- × Poor protection against mucosal disease: Pneumonia, acute otitis media, and nasopharyngeal colonization

Daniels, C. C., Rogers, P. D., & Shelton, C. M. (2016). A Review of Pneumococcal Vaccines: Current Polysaccharide Vaccine Recommendations and Future Protein Antigens. The journal of pediatric pharmacology and therapeutics : JPPT : the official journal of PPAG, 21(1), 27–35. https://doi.org/10.5863/1551-6776-21.1.27

blue water vaccines

Natural History of Infections Caused by Streptococcus pneumoniae



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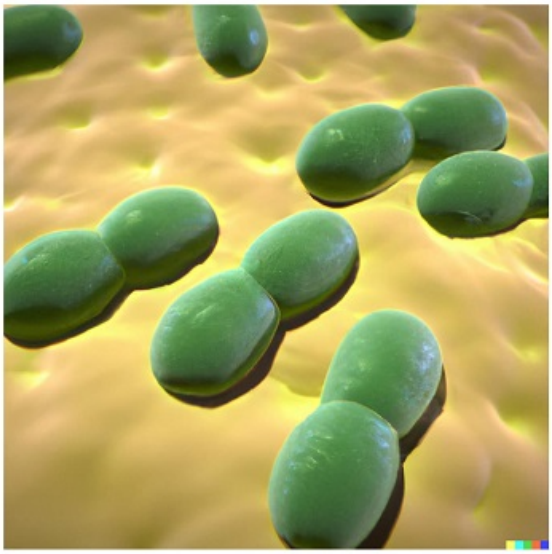
Characteristics of an Ideal, Safe, & Effective Vaccine

- ✓ Highly cross-reactive and serotype independent (Conserved surface proteins)
- ✓ Highly immunogenic and elicits:
  - ✓ Mucosal Immunity: IgA, Th17, Homed B and T-cells
  - ✓ Systemic Immunity: Opsonic IgG, balanced Th1/Th2
- ✓ Efficacious against nasopharyngeal colonization, AOM, and pneumonia in addition to invasive disease
- ✓ Low cost (e.g., to ensure utilization in resource limited settings)
- ✓ Easily delivered
- ✓ Longevity of immune response
- ✓ Localized long-term memory



Berild, J. D., Winje, B. A., Vestrheim, D. F., Slotved, H. C., Valentiner-Branth, P., Roth, A., & Storsäter, J. (2020). A Systematic Review of Studies Published between 2016 and 2019 on the Effectiveness and Efficacy of Pneumococcal Vaccination on Pneumonia and Invasive Pneumococcal Disease in an Elderly Population. Pathogens (Basel, Switzerland), 9(4), 259. https://doi.org/10.3390/pathogens9040259

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Challenges with Live Attenuated Vaccines

- × Deletion of key virulence genes for attenuation also loses key antigens to engender protection
- × Threshold for colonization duration to engender maximal responses – if cleared too rapidly may not induce potent responses
- × Ideal candidate would retain all known virulence factors, colonize for a brief duration, and lack invasive capacity

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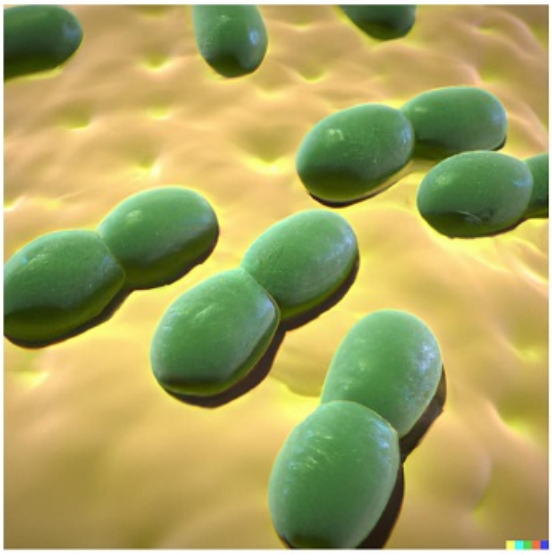
BWV-201: A Live Attenuated Vaccine Candidate

- Noninvasive serotype 19F strain BHN97 which is restricted to mucosal disease
- Deleted *ftsY*, a component *of* the signal recognition particle pathway (SRP) pathway (responsible for delivering membrane and secretory proteins to proper cellular destination), essential in many species
- Vaccine strain BHN97ΔftsY (BWV-201)
  - Attenuated for invasive disease
  - Surface protein content is similar to parental
  - Colonizes murine nasal passages for 3-7 days
  - Induced serotype-independent immune responses



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.

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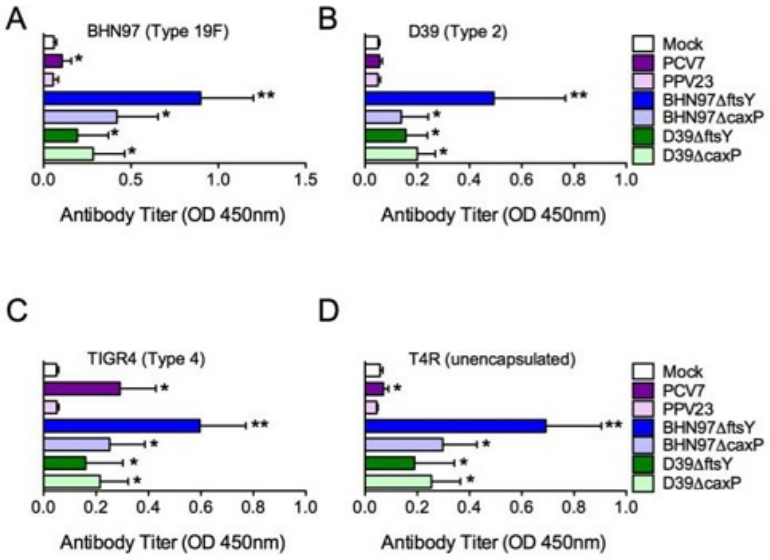
BWV-201: Highly Immunogenic against Homologous and Heterologous Serotypes

Live vaccines induce a potent serotype independent antibody responses



- ELISA against whole bacterial lysates following standard intranasal vaccination schedules in mice
- BHN97 Δ*ftsY* consistently gave the strongest serotype independent responses in a strain and serotype independent manner
- Antibody responses correlated with duration of nasal carriage (BWV-201 colonized longest at 5-7 days)

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.

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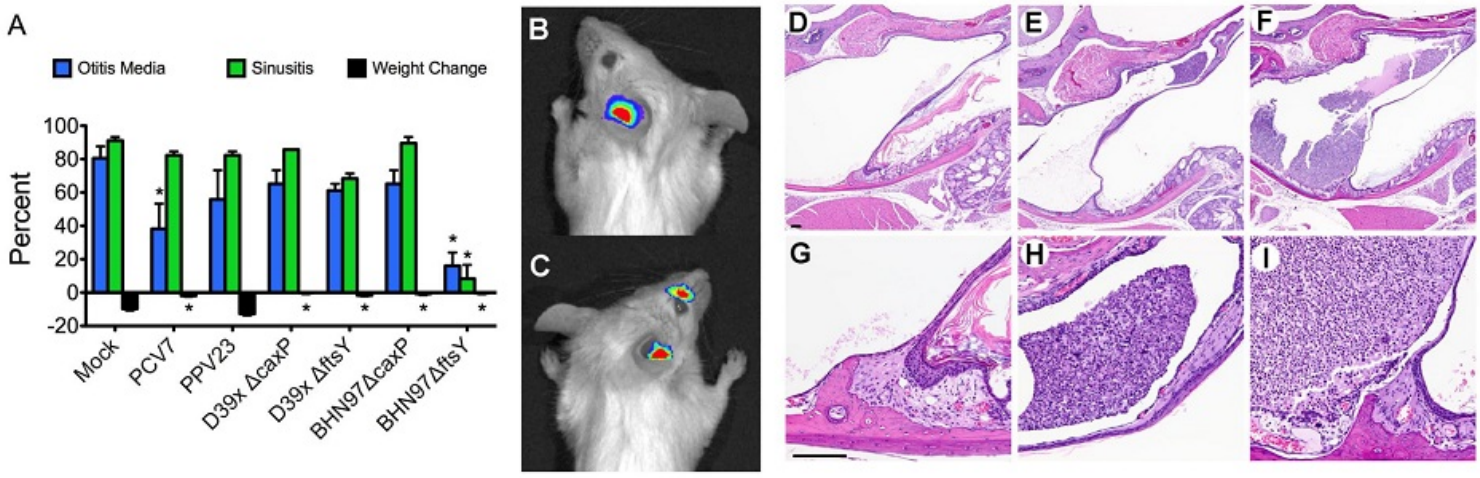
BWV-201: Protected against AOM Caused by Homologous Serotype 19F Challenge



9 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.

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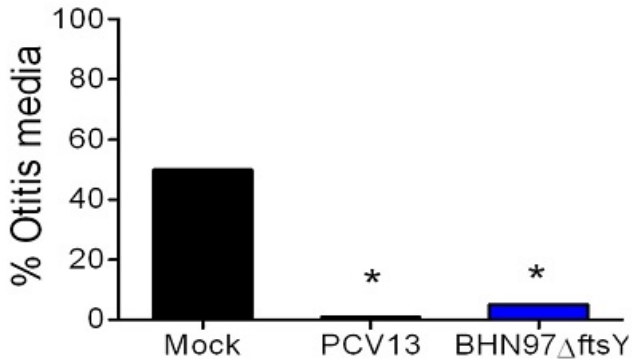
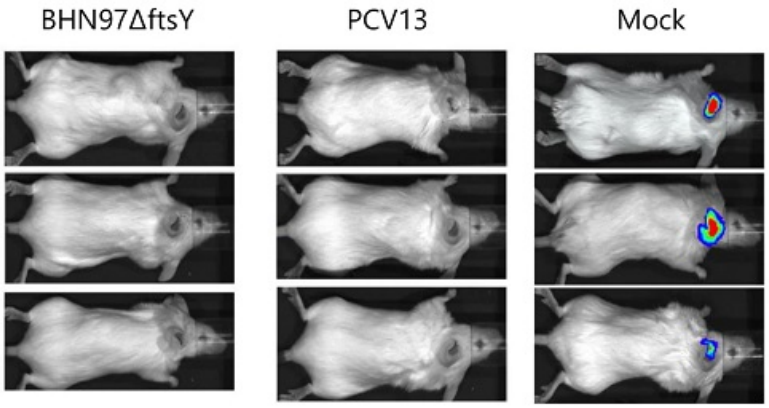
BWV-201: Protected against AOM Caused by Heterologous Serotype 7F Challenge





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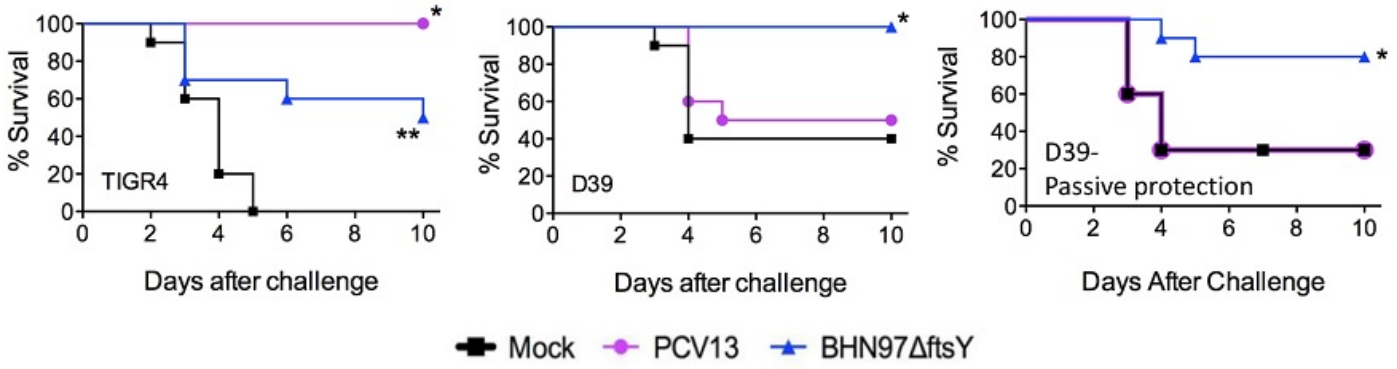
BWV-201: Protected Against IP Challenge (Sepsis/Bacteremia) with Heterologous Serotypes - 4 and 2*



What about the impact of PCV-13 vaccination or prior colonization? Do you dampen the response?

** Non PCV13 serotype*

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.

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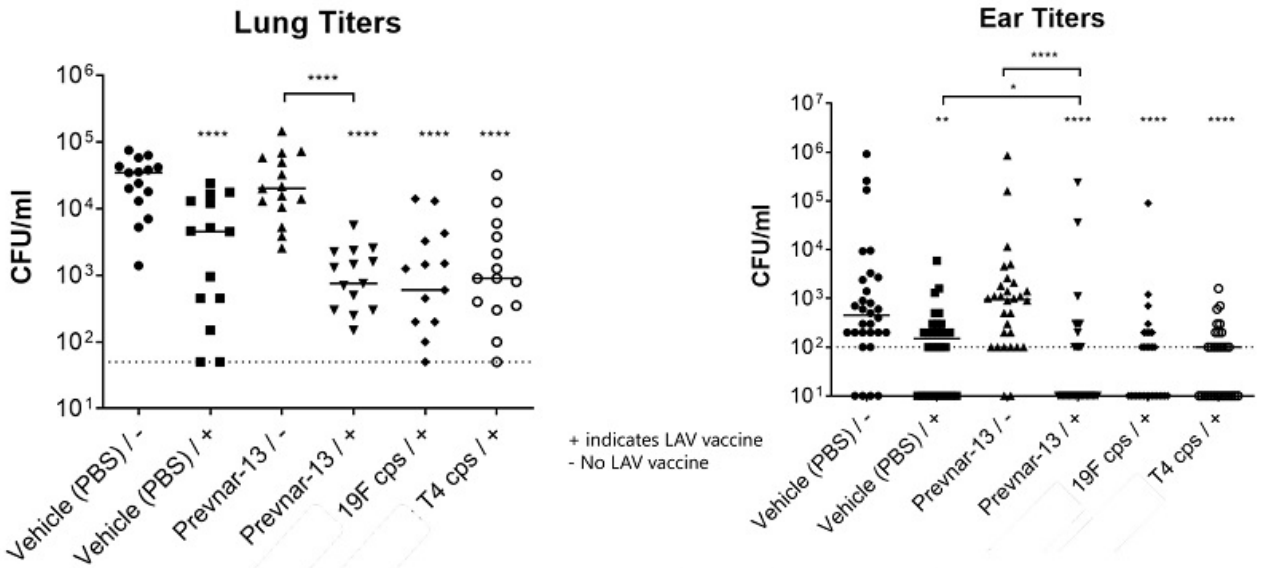
BWV-201: Previous Exposure to Heterologous Infections or PCV Vaccination Enhanced Efficacy (Lungs and Ears)



* = p<0.05, ** = p<0.01, ***p<0.001, **** p<0.0001

12 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.

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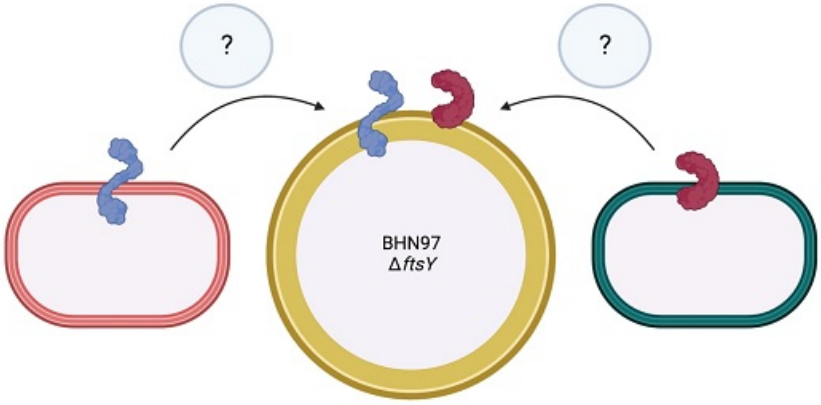
But there are multiple otopathogens…can BWV-201 be modified to confer cross-species protective responses?



Multiple Challenges:

1) Codon optimization and regulation strategies vary dramatically between species

2) Different strategies and mechanisms for protein sorting and localization between different bacterial species, particularly Gram-positive and Gram-negatives

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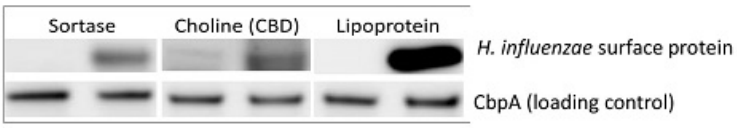
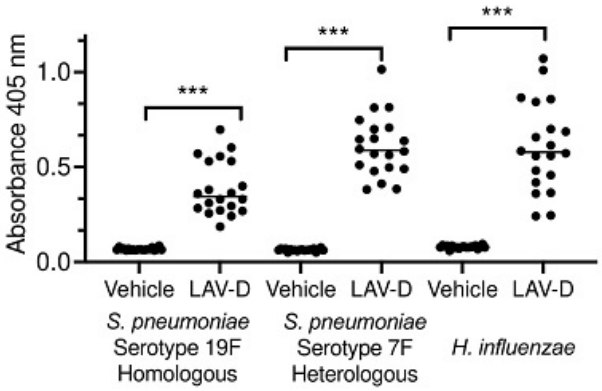
Haemophilus influenzae epitopes successfully expressed and anchored to BWV-201 cell surface via multiple mechanisms





Engineered a strategy by which Gram-negative epitopes can be successfully expressed, sorted, and anchored to the cell surface of vaccine strain via all three predominant mechanisms of surface anchoring in *S. pneumoniae*

*Newly generated data, not yet published

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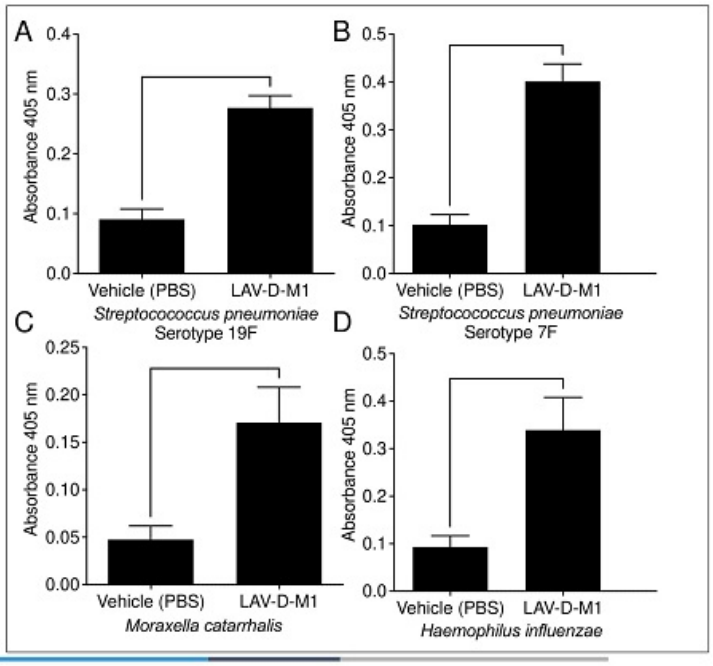
Can this platform be used to deliver multiple antigens from different species to the mucosal surface?



Multiple foreign epitopes can be expressed & are immunogenic *in vivo*

- Engineered live vaccine to express protective epitopes of *Haemophilus influenzae* and *Moraxella catarrhalis* on the cell surface of BWV-201
- Vaccine construct raised antibodies following intranasal vaccination against all three pathogens by ELISA

*Newly generated data, not yet published

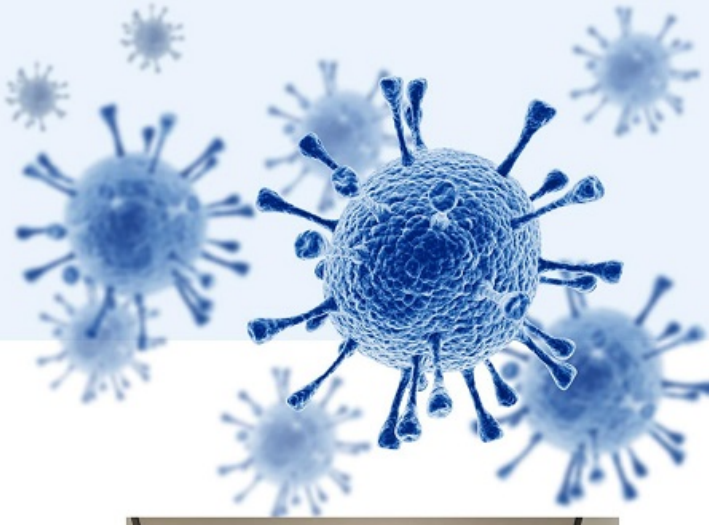
blue water vaccines

Conclusions

- ✓Live attenuated pneumococcal vaccine BWV-201 elicited **robust protection** against both **invasive** (sepsis/bacteremia) and **not invasive** infections (AOM/pneumonia) media
- ✓Protection across **heterologous serotypes**
- ✓**Existing immunity** (vaccination or colonization) is **synergistic** and enhanced protection
- ✓ BWV-201 may serve as a **platform** to include other proteins from multiple bacterial species
- ✓Potential for **combination vaccine** with disease-specific indication AOM or pneumonia caused by different pathogens

blue water vaccines

blue water™
vaccines



Thank you!
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https://twitter.com/vaccinesInc

Rosch Lab Contact: Jason.Rosch@stjude.org