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): October 9, 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 to be held on October 13, 2022 at the World Vaccine Congress held in Barcelona, Spain.

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 8.01 Other Events.

As previously disclosed in the Company's Quarterly Report on Form 10-Q for the period ended June 30, 2022, on April 15, 2022, the Company received a demand letter (the "Demand Letter") from Boustead Securities, LLC ("Boustead"). The Demand Letter alleged that the Company breached its underwriting agreement with Boustead, in connection with the Company's February 2022 initial public offering. The Demand Letter alleged that, by engaging H.C. Wainwright & Co., LLC as placement agent for a private placement financing that closed in April 2022 (the "April Private Placement"), the Company breached Boustead's right of first refusal ("ROFR") to act as placement agent granted to Boustead under the underwriting agreement and, as a result of selling securities in the April Private Placement, breached the Company's obligation under the underwriting agreement not to offer, sell, issue, agree or contract to sell or issue or grant or modify the terms of any option for the sale of, any securities prior to February 17, 2023 (the "Standstill").

On October 9, 2022, the Company and Boustead entered into a Settlement Agreement and Release effective as of September 28, 2022, pursuant to which Boustead agreed to waive the ROFR and the Standstill and to release Company from certain claims with respect to the April Private Placement, the private placement financing closed in August 2022, and all future private, public equity or debt offerings of the Company. As consideration for such waiver, the Company agreed to pay Boustead a cash fee of $1,000,000 plus $50,000 in legal expenses and release Boustead from all claims, subject to certain exceptions. In addition, the Company agreed to issue to Boustead 93,466 shares of restricted common stock in exchange for the cancellation of that certain Representative Warrant, dated February 23, 2022, issued to Boustead.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits

99.1	Presentation, dated October 13, 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: October 12, 2022

By: /s/ Joseph Hernandez

Joseph Hernandez
Chief Executive Officer

blue water™ vaccines

Intranasal Live Attenuated Pneumococcus Vaccine to Protect Against Pneumonia & AOM and Potential Platform for Combination Vaccines

Ali Fattom, Brian Price, Ron Cobb, and Jason Rosch*
Bluewater Vaccines Inc.

NASDAQ: BWV

October 13, 2022

* 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 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.

blue water vaccines

Pneumococcus Vaccines: Success and Limitations

Problem: Pneumococcus causes serious diseases (e.g., acute otitis media, sinusitis, pneumonia, bacteremia, sepsis, meningitis, etc that cause high morbidity and mortality in children and elderly

Success

- ✓ Introduction of the highly efficacious polysaccharide-conjugate vaccines (e.g., Prevnar series, Synflorix, etc.) reduced pneumococcus infections dramatically

Limitations

- × Protection is serotype specific
- × Efficacy was almost exclusive to invasive diseases; Bacteremia, sepsis, and meningitis
- × Emergence of non-vaccine type in the community
- × Cost and availability in LMIC
- × Poor protection against major infections: Pneumonia, AOM, and nasopharyngeal colonization

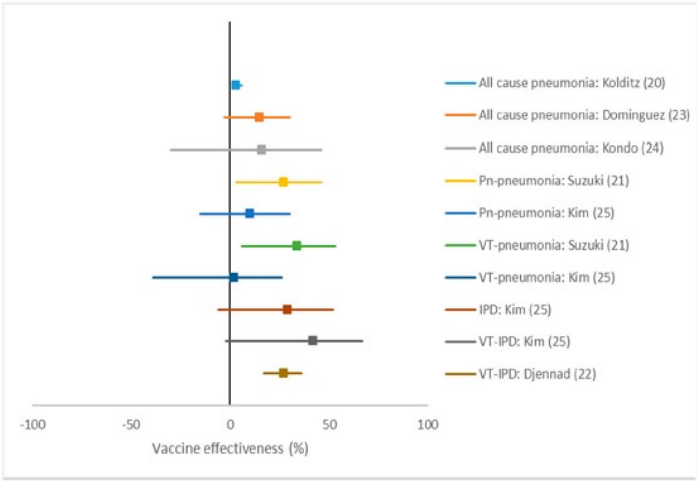
Moffitt &Malley, 2016

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

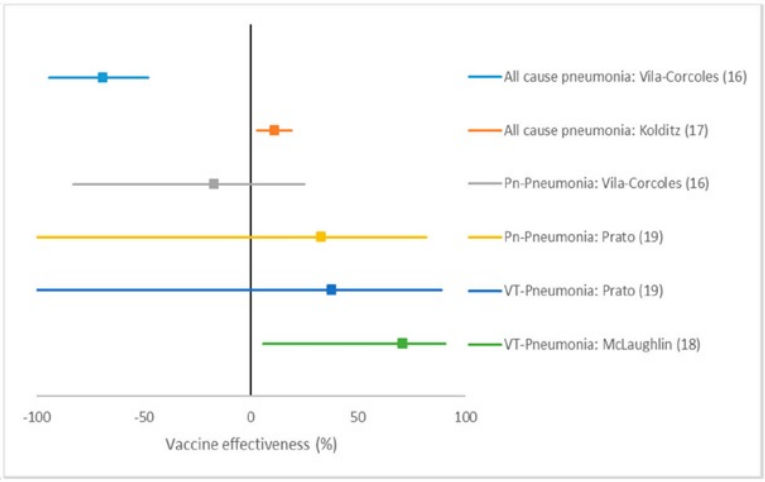
blue water vaccines

PPV23 and PCV13 Vaccines Effectiveness Against *S. pneumonia* in Elderly

PPV23 Pneumococcal Pneumonia Efficacy Rates



PCV13 Pneumococcal Pneumonia Efficacy Rates



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

blue water vaccines

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
- ✓ Low cost (e.g., to ensure utilization in LMICs)
- ✓ 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

blue water vaccines

BWV-201: A Live Attenuated Vaccine Candidate

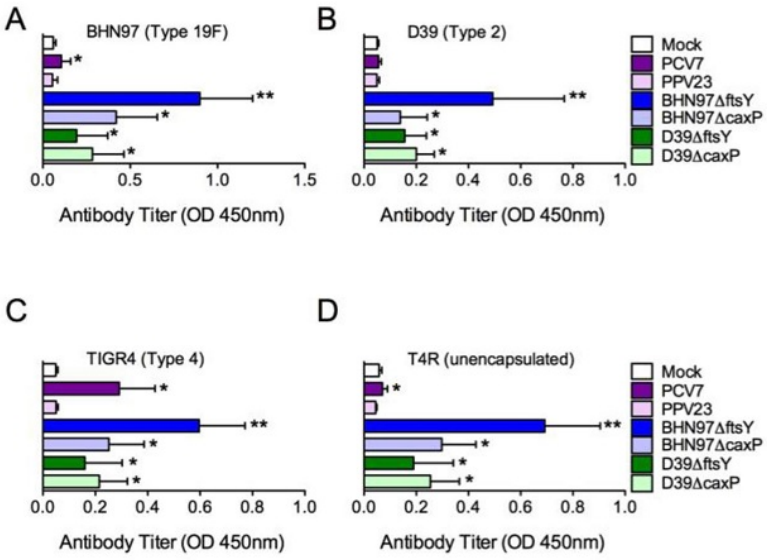
- Noninvasive serotype 19F strain BHN97 which normally causes sinusitis/purulent rhinitis and AOM
- Deleted *ftsY, a component of* the signal recognition particle pathway (SRP) pathway (*responsible for delivering membrane and secretory proteins to proper cellular destination*)
- Vaccine strain BHN97ΔftsY
  - Attenuated for invasive disease
  - Deficient for competence/recombination
  - Surface protein content is similar to the WT
  - Colonizes murine nasal passages for 3-7 days
  - Induced serotype-independent immune response

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.

blue water vaccines

BWV-201: Highly Immunogenic against Homologous and Heterologous Serotypes

Live vaccines induce a potent serotype independent antibody responses

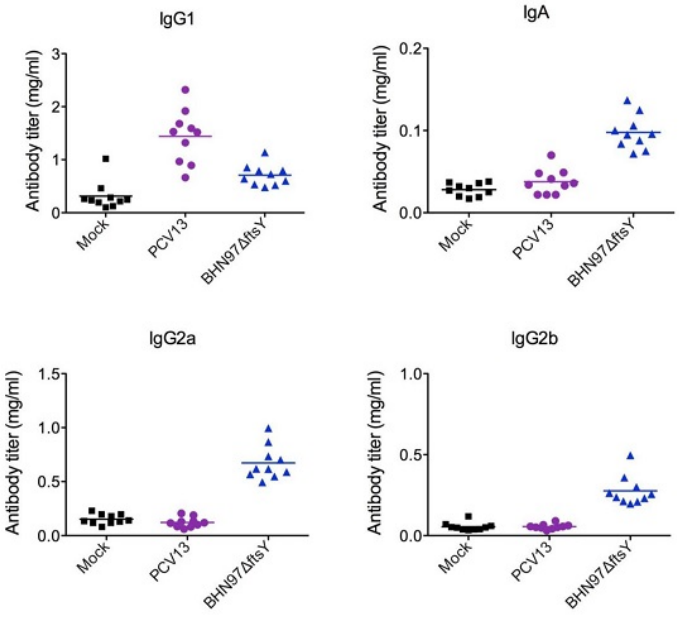


- ELISA against whole bacterial lysates following standard vaccination schedules in mice
- BHN97 ΔftsY consistently gave the strongest serotype independent responses in a strain and serotype independent manner

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.

blue water vaccines

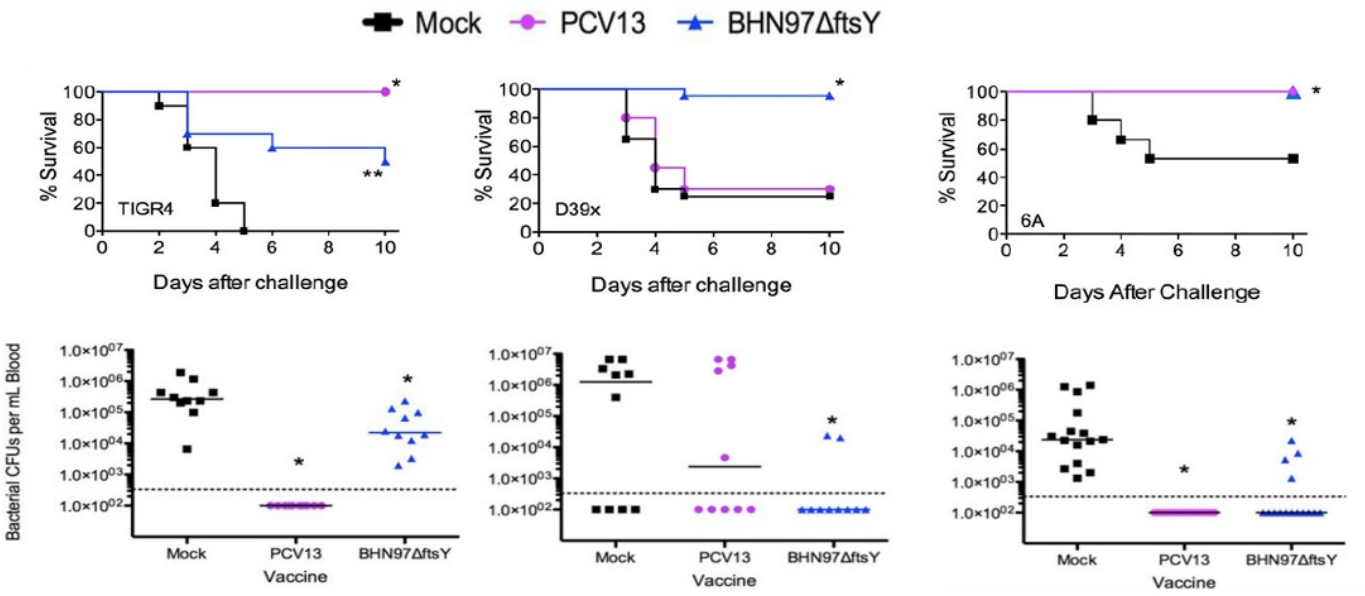
BWV-201: Induction of a Balanced Th1/Th2 and Mucosal Immunity



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.

blue water vaccines

BWV-201: Protected Against IP Challenge (Sepsis/Bacteremia*) with Heterologous Serotypes - 4 , 2, and 6A



** Blood obtained at 24hrs Post IN challenge*

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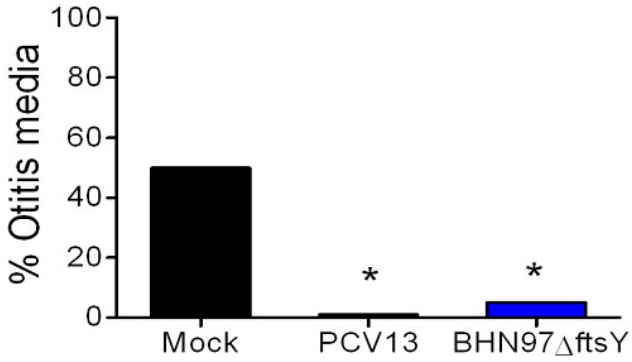
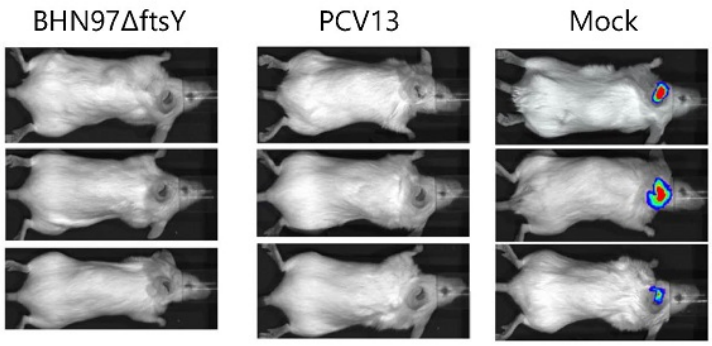
BWV-201: Protected against AOM Caused by Serotype 7F Challenge



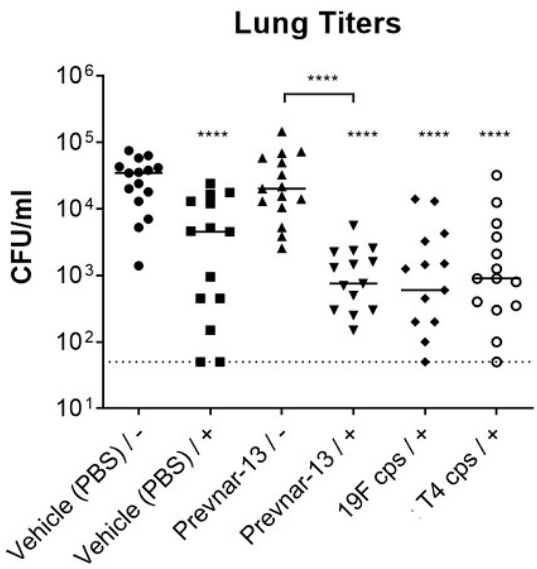


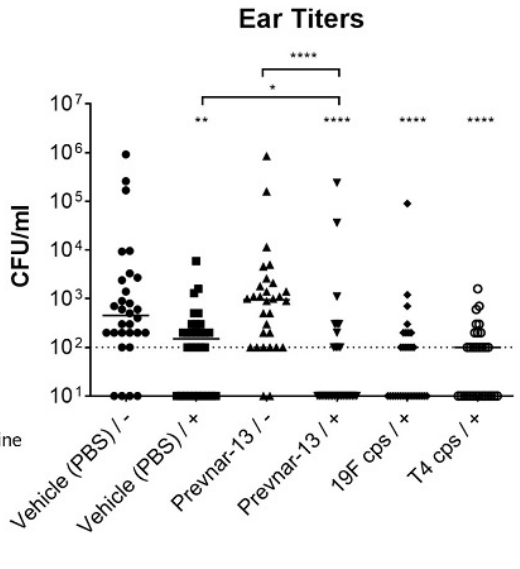
Rosch J, 2013

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.

blue water vaccines

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





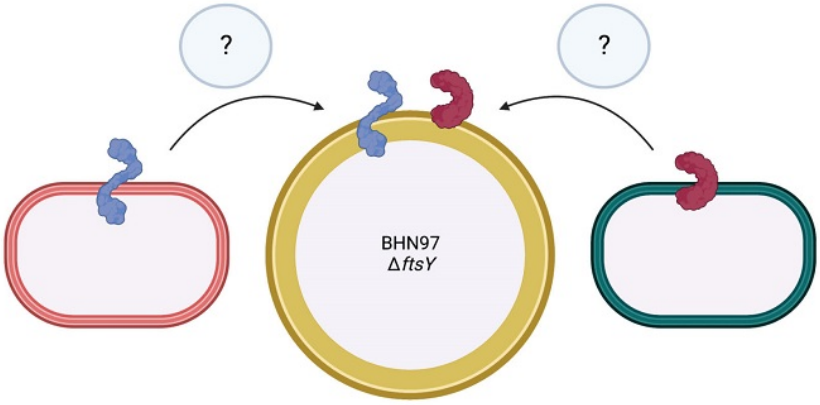
+ indicates LAV vaccine
- No LAV vaccine

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

*Newly generated data, not yet published

blue water vaccines

BHN97Δ*ftsY*: A Potential Platform for Combination Vaccines



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

*Newly generated data, not yet published

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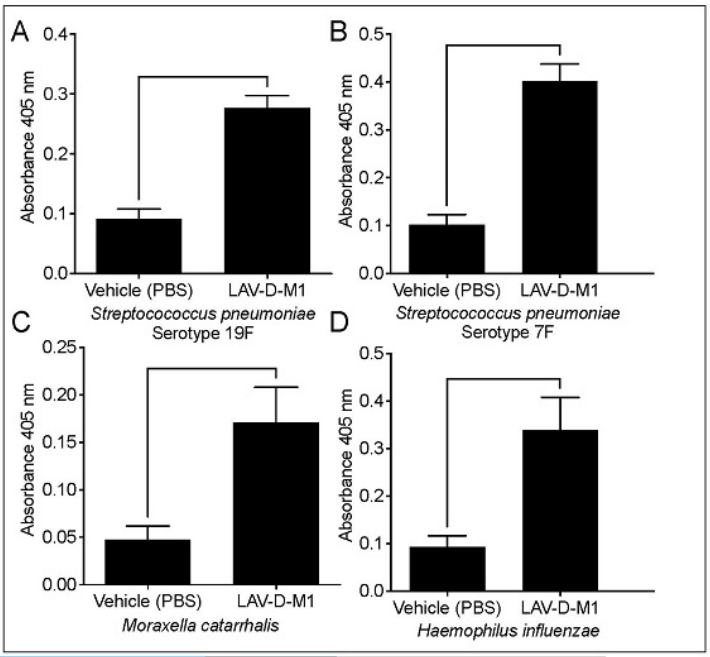
Can this platform be used to deliver multiple antigens from different species to the mucosal surface?



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 the live vaccines strain of pneumococcus
- Vaccine construct raised antibodies following intranasal vaccination against all three pathogens by ELISA

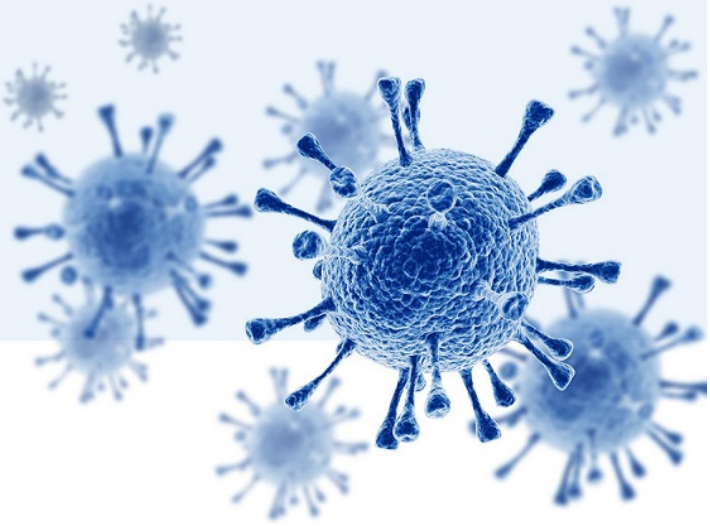
*Newly generated data, not yet published

Conclusions

- ✓Live attenuated pneumococcal vaccines 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