UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 8-K

CURRENT REPORT

Pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934

Date of Report (Date of earliest event reported): May 15, 2023

Blue Water Biotech, 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.

As previously announced on May 10, 2023, the management of Blue Water Biotech, Inc., a Delaware corporation (the "Company"), will present at the JMP Securities Life Sciences Conference at the New York Hilton Midtown on Monday, May 15, 2023 (the "JMP Conference"). The Company's presentation, which was originally scheduled for 3:30 p.m. EDT, has been moved to 11:00 a.m. EDT. In addition, the form of the slide presentation the Company intends to use at the JMP Conference (the "Presentation") is attached hereto as Exhibit 99.1 and is being furnished herewith.

The information in this Item 7.01 of this Current Report on Form 8-K (this "Current Report") and the Presentation being furnished herewith shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, or otherwise subject to the liabilities of that section or Sections 11 and 12(a)(2) of the Securities Act of 1933, as amended. The information contained in this Item 7.01 and in the Presentation attached as Exhibit 99.1 to this Current Report shall not be incorporated by reference into any filing with the SEC made by the Company, whether made before or after the date hereof, regardless of any general incorporation language in such filing.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits

99.1	Presentation, dated May 2023.
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 duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

Blue Water Biotech, Inc.

Date: May 15, 2023

/s/ Joseph Hernandez
Joseph Hernandez
Chief Executive Officer

Exhibit 99.1

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Corporate Overview & ENTADFI® Opportunity

May 2023
NASDAQ: BWV

Forward Looking Statements

The Presentation (the "Presentation") has been prepared by Blue Water Biotech, 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 Biotech, 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 Blue Water 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, the Company's ability to commercialize ENTADFI®; market acceptance of the Company's products and product candidates; the size and growth of the potential markets for the Company's products and product candidates and its ability to serve those markets; the development of Blue Water'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. Blue Water does not undertake an obligation to update or revise any forward-looking statement. Investors should read the risk factors set forth in Blue Water Annual Report on Form 10-K for the fiscal year ended December 31, 2022, filed with the Securities and Exchange Commission (the "SEC") on March 9, 2023 and periodic reports filed with the SEC on or after the date thereof. All of Blue Water 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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Executive Summary

1 **Experienced Management Team**

2 **Substantial Opportunity with ENTADFI**

- *FDA-approved to treat BPH*
- *BPH represents significant market opportunity*
- *Official commercialization launch anticipated in Q3 2023*

3 **Robust Vaccine Pipeline**

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Blue Water Biotech Overview

Broad and Diverse Vaccine Pipeline

Vaccines against acute otitis media, pneumonia, influenza, norovirus, rotavirus, chlamydia and malaria

Commercial Product Acquisition & Launch

Recent purchase of ENTADFI® highlights transition of Blue Water Biotech into a commercial company

Accomplished Management & Board of Directors

Management team and board of directors with extensive and diverse industry experience

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Focus on Diseases with High Unmet Need

Targeting high-burden diseases & conditions that impact millions of lives globally

Esteemed Research Collaborations

University of Oxford, Cincinnati Children's Hospital Medical Center, St. Jude Children's Research Hospital, & UT Health San Antonio

Opportunistic Business Model & Corporate Strategy

Exclusive licenses of assets & platforms and targeted business development efforts

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Accomplished Management Team

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

Joseph Hernandez
Founder, Chairman & CEO

Andrew Skibo
Head of Biologic Operations

Ali Fattom, Ph.D.
Head of Science and Discovery

Erin Henderson
Chief Business Officer

Jon Garfield
Chief Financial Officer

Frank Jaeger
SVP of Marketing & Business Development

Prior Management Experience

MERCK · AstraZeneca · NIH · NABI BIOPHARMACEUTICALS · ORAGENICS · MedImmune · Coach USA · AETOS GROUP · BlueWillow Biologics · pwc · abbvie · clarus THERAPEUTICS

Notable Products

FluMist Quadrivalent (Influenza Vaccine Live, Intranasal) · AndroGel (testosterone gel) 1.62% · GARDASIL 9 [Human Papillomavirus 9-valent Vaccine, Recombinant] · JATENZO (testosterone undecanoate) Capsules · FOSAMAX (alendronate sodium) · TRUE ONCE-DAILY VIOXX (rofecoxib, MSD) · SINGULAIR (montelukast sodium)

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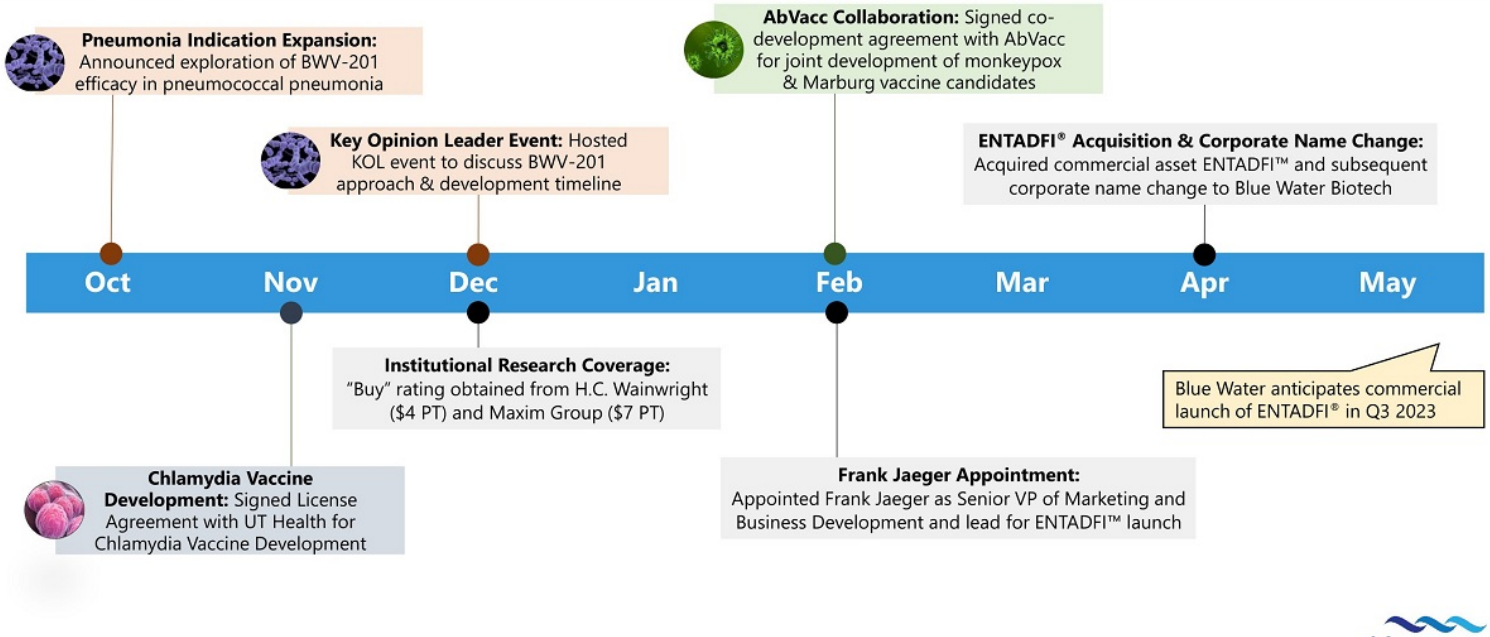
Recent Vaccine Program Execution and Corporate Growth, Highlighted by Recent Purchase of ENTADFI®



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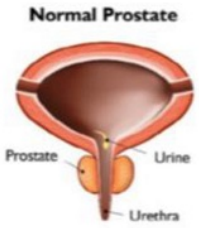
ENTADFI®
A Transformative Opportunity

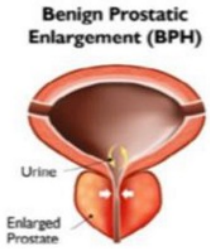
Benign Prostatic Hyperplasia (BPH) Overview

Delay in symptom relief and sexual adverse effects lead to poor adherence of current BPH treatments

Benign Prostatic Hyperplasia – The Disease

- Histologic prevalence globally is thought to be ask high as 50% for men in their 50s, 70% for men in their 60s, and 80% for men 70 years of age or older[1]
- Medical management is most common treatment option for symptomatic disease
- Common BPH symptoms include frequency, urgency, and an inability to void
- Up to 70% of BPH patients have erectile dysfunction[2]
- Per IQVIA, 44M US BPH prescriptions were filled in 2022
- Prescriptions are written by both primary care and urology





BPH – The Need

- No current BPH prescriptions provide symptom relief, prostate size reduction, and ED treatment
- ENTADFI® will be the ***first line*** prescription to treat BPH symptoms, reduce prostate size, and manage ED symptoms

Total US BPH Target Population of 55.1 Million Men 50+ Years of Age[1,3]

References: 1. Yale Medicine (https://www.yalemedicine.org/conditions/enlarged-prostate-benign-prostatic-hyperplasia-bph); 2. Oelke M, Bachmann A, Descazeaud A, Emberton M, Gravas S, Michel MC, et al. EAU Guidelines on treatment and follow up of non-neurogenic male lower urinary tract symptoms including benign prostatic obstruction. *Eur Urol.* 2013;64:118–40. 3. Resident Population of the US by sex and age as of July 1, 2021 (https://www.statista.com/statistics/241488/population-of-the-us-by-sex-and-age/).

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The ENTADFI Opportunity

ENTADFI has the potential to be first-line tx for BPH symptoms, reducing prostate size and managing ED

- **Current BPH treatment can take up to 6-12 months for significant symptom relief**, contributing to adherence concerns[1]
- **Men with moderate-to-severe LUTS are at increased risk for sexual dysfunction**, including erectile dysfunction, ejaculatory dysfunction, and hypoactive desire[2]
- LUTS/BPH severity and number of medications influence adherence rates
  - Men with less severe symptoms have poorer adherence[3]
  - **Men taking multiple BPH treatments concurrently had an adherence rate of 9%**[4]
- Several **BPH treatments significantly increased the risk of ED, ejaculatory dysfunction, and hypoactive sexual desire** in subjects with BPH[3,4]
- AEs related to sexual/ejaculatory dysfunction appear to increase with 5-ARI/ α-blocker coadministration[1]

Lower urinary tract symptom improvement is not observed with finasteride monotherapy for 6 to 12 months and a-blockers are not indicated to reduce prostate size[1]

5-ARI – 5-alpha reductase inhibitor; AE – adverse events; BPH – benign prostatic hyperplasia; ED – erectile dysfunction; LUTS – lower urinary tract symptoms.

References: 1. Casabé A et al. *Journal of Urology*. 191:727-733 2014. **2.** Rosen RC, et al. *European Urology*. 2005;47(6):824-837. **3.** Zabkowski T, Saracyn M. *J Physiol Pharmacol*. 2018;69(4):10.26402/jpp.2018.4.14. **4.** Cindolo L, et al. *European Urology*. 2015;68(3):418-425. **5.** Shin YS, et al. *World Journal of Men's Health*. 2019;37(2):157-165. **6.** Corona G, et al. *Andrology*. 2017;5(4):671-678.

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ENTADFI® is the First and Only FDA-Approved Combination Therapy for BPH

ENTADFI® (tadalafil and finasteride) capsules

Tadalafil + Finasteride = ENTADFI® (tadalafil and finasteride) capsules

Key Differentiators

- **Dual MOA**
- **Faster & improved LUTS**
- **Significant 1° & 2° endpoints** (at all time points)
- **Greater relief of LUTS**
- **Sustained over 26 weeks**
- **> Treatment satisfaction at week 26**

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ENTADFI® Significantly Improves Early BPH Symptoms

International Prostate Symptom Score (IPSS): an eight-question self-administered survey used to screen for, diagnose, track, and manage the symptoms of BPH. Higher scores correlate with more severe symptoms and decreased QoL

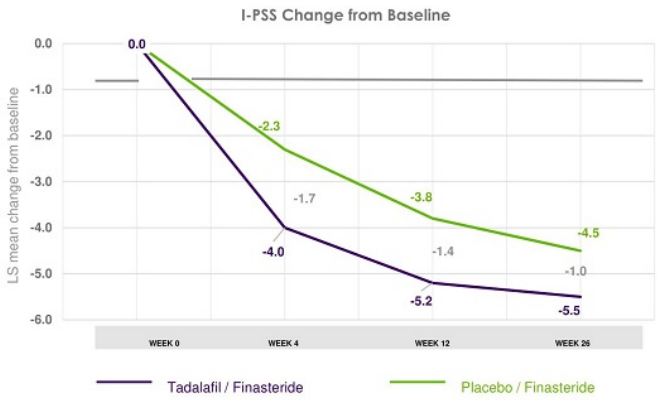
Primary Endpoint Achieved

- LS mean change from baseline with TAD/FIN at 12 weeks was -5.2 vs -3.8 for PBO/FIN (LSTD of -1.4 [95% CI -2.3, -0.6; p ≤0.001])

Key Secondary Endpoints Were Statistically Significant

- Significant LUTS improvements were observed with TAD/FIN at 4 and 26 weeks after baseline
- LS mean change in I-PSS total score
  - Week 4: TAD/FIN was -4.0 vs -2.3 for PBO/FIN (p <0.001)
  - Week 26: TAD/FIN was -5.5 vs -4.5 for PBO/FIN (p = 0.022)

Time course of LS mean change from baseline in I-PSS total score



TAD/FIN Led to a 74% Greater Reduction than Finasteride Alone Within the First 4 Weeks and a 22% Greater Reduction at Week 26

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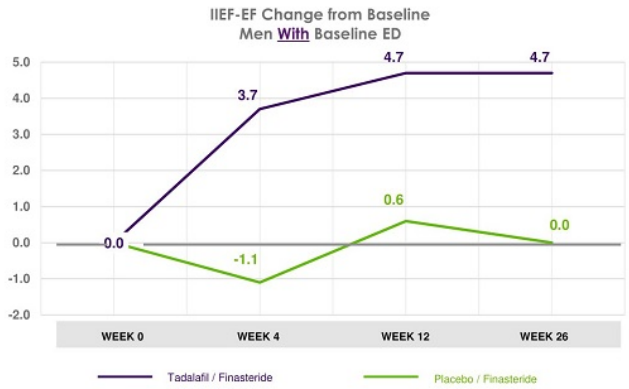
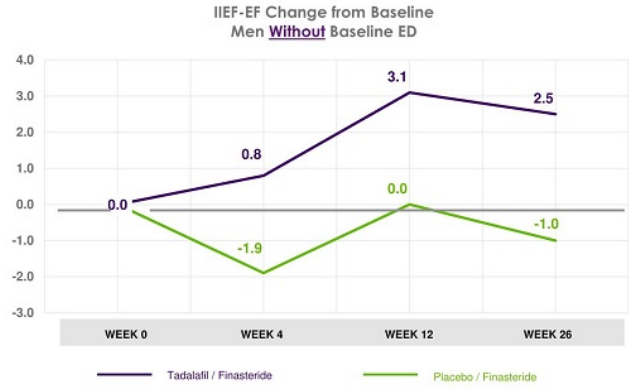
ENTADFI® Significantly Improves Sexual Function in Men

Among Sexually Active Men With and Without Baseline ED Treated with TAD/FIN, Significant Improvements Were Observed in Scores at All Three Postbaseline Timepoints that were Significantly Greater than Patients Treated with PBO/FIN[1,2]

The International Index of Erectile Function (IIEF): a widely-used multidimensional evaluation for male sexual function. A self-administered questionnaire that reliably assesses sexual function & satisfaction to help inform HCPs of sexual symptoms associated with BPH





BPH – benign prostatic hyperplasia; ED – erectile dysfunction; FIN – finasteride; HCP – healthcare provider; IIEF – International Index of Erectile Function; LS – least square;; PBO – placebo; TAD – tadalafil.

References: 1. Casabé A et al. *Journal of Urology*. 191:727-733 2014. **2.** Glina et al. *J Sex Med*. 2015;12:129–138.

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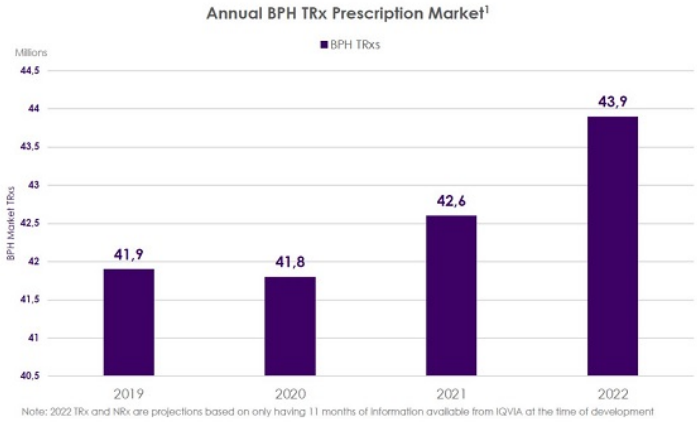
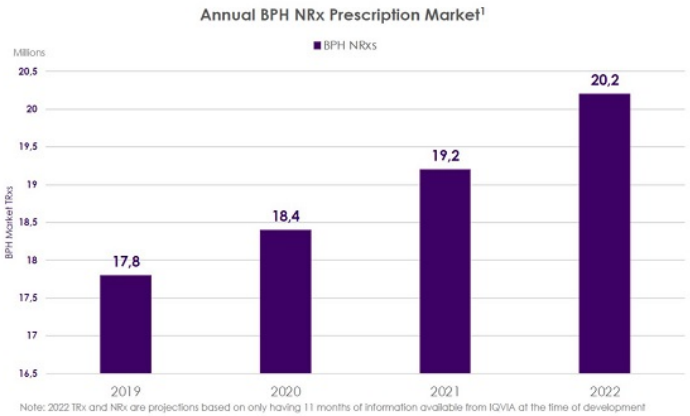
Maximizing ENTADFI® Potential

At Close to 44 MM TRx Written Per Year, the BPH Market is Large and Growing





References: 1. IQVIA Annual BPH Market – January'23.

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Treatment of Lower Urinary Tract Symptoms Still Remains Problematic in the United States

Medicare was estimated to have spent more than $1.5 billion on in-office and outpatient services related to LUTS-BPH[1]

Approximate Medicare annual in-office and outpatient BPH service costs[1]

$1.5 BILLION

23% of all urologic office visits	**41.2%** of privately insured BPH patients	**12.2M** actively managed with BPH treatment
BPH treatment and diagnosis make up the largest segment of urologic practice[2]	41.2% of privately insured BPH patients filled at least one BPH-related prescription[1]	54.8% of 12.2M actively managed BPH patients are managed with pharmacological therapy[2]

Source: 1. Feinstein L., Matlaga B. US Department of Health and Human Services, Public Health Service, National Institutes of Health, National Institute of Diabetes and Digestive and Kidney Diseases; 2018; NIH Publication No. 12–7865 [pp. 78–81]. 2. Vuichoud, C. Canadian Journal of Urology 22.Suppl 1 (2015): 1-6.

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Market Research

ENTADFI's product profile highly accepted by Urologists indicating quick adoption

"I think it's a great idea. A lot of doctors may combine these therapies already. Whenever I think about these products--you know both these drugs you can find generic now so I kind of understand why they try and combine it too, my opinion on the actual utility of the drug I think it definitely has a strong indication that can be useful in lots of patients. I think its definitely useful."

"I am using this combo but if somebody was on this combo likely they would be on all 3 meds, an alpha, a PDE5 and an ARI because somebody is so symptomatic that I'm putting them on a second med in addition to something to shrink their prostate. I need something to relax their prostate as well. Its likely they're symptomatic enough that I'm going to put them on all 3. and usually, this would be someone with ED. I can see how it would be useful."

"I mean we use this combo. It can be somebody on the alpha blocker and this combo. And it could be helpful. And I suppose that instead of the alpha blocker and finasteride the tadalafil and finasteride could kind of be in the same tier in terms of trying to help. I could see it being used."

"In particular I think it would be appropriate in a gentleman with a prostate gland size that's greater than 35 mL by digital rectal exam and also coincident ED."

"My initial thoughts are the same thoughts as when Jayln came out. A combo of drugs that we're already using, at that point it was 5-ARI and alpha blocker. These are drugs used fairly commonly so to have it combined in a single product would be beneficial."

Source: Integrated Insights Consulting ENTADFI™ Messaging Research; *n*=25; July 2022

Three-Pronged Strategy to Commercialize ENTADFI® and Transform Blue Water Biotech

HCP Education Consumer Education Partnerships

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Potential Men's Health Strategic Partners

Direct to Consumer

Reaching diagnosed and treated patients to educate on ENTADFI

Direct-to-consumer advertising

Patient awareness

Patient demand

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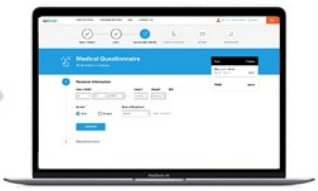
Telemedicine & HUB Approach

An opportunity to virtually speak to a healthcare provider and get ENTADFI shipped direct

Inquire



Qualify

Transact

Ship

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Healthcare Provider Focus

Hyper-focused Targeting directed to top decile Urologists

Decile	Total Rx's	Total URO	Rx per HCP
10	1,046,034	229	4,568
9	1,044,673	327	3,195
8	1,044,958	402	2,599
7	1,043,744	470	2,221
6	1,049,786	553	1,898
5	1,045,625	648	1,614
4	1,040,716	766	1,359
3	1,043,213	960	1,087
2	1,043,741	1,334	782
1	1,043,245	7,069	148

~2,600 HCP's fall into Urology Deciles 5-10

* 2023 Deciling, IQVia LRx claims

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Intellectual Property

Unique formulation and manufacturing know-how creates barrier to entry by generic competition

Unique ENTADFI Formulation & Manufacturing Know How

- Combination products difficult to formulate creating barrier to entry by generic competitors
- Unique proprietary information developed by Veru required to overcome significant physiochemical challenges to demonstrate 505b2 bioequivalence (Cmax, Tmax, AUC)
- Zentiva (formerly Sanofi) filed European dossier with EMA in 12/21 for tadalafil and finasteride combination product and still no EMA approval!

BPH – benign prostatic hyperplasia; LUTS – lower urinary tract symptoms.

References: 1. Casabé A et al. *Journal of Urology*. 191:727-733 2014. **2.** Elkelany O et al. *Ther Clin Risk Manag*. 2015;11:507-513. **3.** Glina et al. *J Sex Med*. 2015;12:129–138.

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Our Vaccine Candidates

Broad and Diverse Vaccines Pipeline

Infectious Disease Program	Candidate	Preclinical	Phase 1	Phase 2	Phase 3	Collaborator
S. pneumo-Induced Acute Otitis Media & Pneumonia	BWV-201					St. Jude Children's Research Hospital
Universal Flu	BWV-101					University of Oxford
H1 Pre-Pandemic	BWV-102					
Norovirus / Rotavirus	BWV-301					Cincinnati Children's
Malaria	BWV-302					
Monkeypox	AbVacc Collaboration					Cincinnati Children's
Marburg	AbVacc Collaboration					AbVacc
Chlamydia	BWV-401					UT Health San Antonio

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Renowned Research Partners

Sunetra Gupta, Ph.D.

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

Professor, University of Oxford

Xi Jason Jiang, Ph.D.

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

Retired Professor, University of Cincinnati, Department of Pediatrics

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

Guangming Zhong, M.D., Ph.D.

Inventor, Chlamydia Vaccine (BWV-401)

Professor, University of Texas Health San Antonio

Targeted Vaccine Pipeline to Address High Disease Burden and Areas Without Efficacious Vaccines

BWV Program	Target Indication	Market Size	Current Development Phase
BWV-201	AOM & Pneumonia	**AOM**: $4B spent on treatment annually[1] **Pneumonia**: $1.3B in direct medical costs in the US annually[2]	Preclinical, cGMP Manufacturing-Ready
BWV-101	Universal Flu	Total annual economic burden due to influenza is approximately $87B in the US alone[3]	Preclinical, Epitope Optimization
BWV-102	H1 Pre-Pandemic	Limited ability to develop pre-pandemic vaccines given yearly reformations of vaccines & lack of broad vaccine coverage	Preclinical, Epitope Optimization
BWV-301	Norovirus / Rotavirus	**Norovirus:** 700 million cases[4] & $60.3B spent worldwide annually[5] **Rotavirus:** 111 million cases each year & limited vaccine efficacy in LIC[6]	Preclinical, VLP Expression
BWV-302	Malaria	$12B in direct medical costs worldwide each year[7], limited vaccine available vaccines[8]	Preclinical, VLP Optimization
BWV-401	Chlamydia	1.6 million cases in the US each year[9], 129 million globally[10], no current vaccines available[11]	NHP Study in 2023

1) Tang 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 Health Serv Res. 2018 May 2;18(1):318. doi: 10.1186/s12913-018-3139-1. PMID: 29720156; PMCID: PMC5932897.
2) CDC. Drug Resistant Streptococcus Pneumoniae. https://www.cdc.gov/drugresistance/pdf/threats-report/strep-pneumoniae-508.pdf
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, "Norovirus Worldwide".
6) World Health Organization, "Rotavirus Vaccines: WHO position paper – July 2021"
7) Centers for Disease Control and Prevention, "Malaria's Impact Worldwide"
8) World Health Organization, "WHO recommends groundbreaking malaria vaccine for children at risk", 6 October 2021
9) Centers for Disease Control and Prevention, "The State of STDs in the United States in 2021"
10) World Health Organization, Fact Sheets, "Sexually Transmitted Infections (STIs)"
11) Centers for Disease Control and Prevention, "Chlamydia Treatment & Care"

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Executive Summary

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Thank you!

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https://www.linkedin.com/company/blue-water-biotech-inc

https://twitter.com/BlueWater_Bio