Blue Water Vaccines Reports Year 2022 Financial Results and Recent Business Highlights

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CINCINNATI, March 09, 2023 (GLOBE NEWSWIRE) -- Blue Water Vaccines Inc. (“BWV” or “Blue Water Vaccines” or the “Company”), today announced its financial results for the fiscal year ended December 31, 2022 and provided an update on recent business developments and Company progress. Blue Water Vaccines is a preclinical stage biotechnology company developing vaccines against multiple infectious diseases, including acute otitis media (“AOM”) and pneumonia from *Streptococcus pneumoniae* colonization, influenza, norovirus, rotavirus, monkeypox, Marburg virus disease and Chlamydia.

“In addition to our successful initial public offering and raising subsequent capital to extend our runway, we made significant corporate progress and further developed our vaccine candidates throughout the year,” said Joseph Hernandez, Chairman and Chief Executive Officer of Blue Water Vaccines. “We advanced research of our *Streptococcus pneumoniae* vaccine candidate, expanded its target indication to include both acute otitis media and pneumococcal pneumonia, and are exploring the potential to transform this vaccine into a platform to protect against other respiratory pathogens. In addition, we continued to expand our research endeavors with our esteemed network of collaborators and highlighted our story to investment and scientific conferences around the world. We are truly excited to build on this progress in 2023 and continue our mission to positively impact public health for all.”

2022 and Recent Corporate Developments

- In February 2022, BWV closed its initial public offering of 2,222,222 shares of common stock, generating aggregate net proceeds of approximately $17.1 million.
- BWV closed private placements in each of April and August of 2022, with aggregate net cash proceeds of approximately $6.9 million and $8.7 million, respectively.
- In November 2022, the Board approved a share repurchase program to allow for the Company to repurchase up to 5 million shares, with discretion to management to make purchases subject to market conditions.
- BWV named several seasoned professionals to its board of directors, including Simon Tarsh, retired Deloitte consulting Senior Managing Director, Vuk Jeremić, previous chair of the Council of Europe’s Committee of Ministers and previous President of the United Nations Assembly, as well as Timothy Ramdeen, experienced public market and private equity investment leader.
- In February 2023, BWV appointed veteran commercial operations leader Frank Jaeger as Senior Vice President of Marketing and Business Development to support BWV as its pipeline programs progress towards clinical development.
- In December 2022, BWV received “buy” recommendations from two notable healthcare-focused Wall Street banks, Maxim Group LLC and H.C. Wainwright & Co.
- Throughout 2022 and into the first quarter of 2023, BWV management presented its corporate overview and Company updates at key investor and financial conferences to highlight the value story of the BWV pipeline and target leaders within the investment community.

2022 and Recent Vaccine Candidate Developments

- On October 11, 2022, the Company announced plans to evaluate the ability of BWV-201, a live attenuated Streptococcus pneumoniae vaccine candidate, to protect individuals against non-invasive pneumococcal pneumonia in children and adults. Given BWV-201 is delivered intranasally, rather than intramuscularly like the current pneumococcal vaccines on the market,

BWV-201 is designed to elicit mucosal immunity and protect against disease in the lungs.

- In December 2022, BWV signed an exclusive, global license agreement for a novel Chlamydia vaccine candidate from the University of Texas Health at San Antonio. Currently, there are no available vaccines to prevent Chlamydia infection and the main treatment is through antibiotic regimens. Chlamydia is the most frequently reported bacterial sexually transmitted infection in the United States, with about 1.6 million new cases reported in 2020 alone, and globally, there are an estimated 129 million cases each year. BWV's novel vaccine candidate is a live attenuated Chlamydia strain delivered orally and is hypothesized to provide transmucosal protection in the genital tract to prevent disease.
- Throughout 2022 and into the first quarter of 2023, BWV expanded the exploration of the applicability of its virus-like particle ("VLP") platform into multiple disease indications. Based on technology from Cincinnati Children's Hospital Medical Center ("Cincinnati Children's"), BWV's VLP platform utilizes norovirus shell and protrusion particles to self-assemble into VLPs, capable of presenting antigens from various infectious diseases to create novel vaccine candidates.
    - In March 2022, VLP licensing partner Cincinnati Children's published a research paper in *Nano Research* supporting the utilization of the VLP platform to present influenza antigens. BWV intends to explore the addition of its epitopes of limited variability, which serve as the basis for BWV's universal influenza vaccine candidate, BWV-101, and pre-pandemic H1 vaccine, BWV-102, into the VLP platform for vaccine development.
    - In February 2023, BWV announced a collaboration with AbVacc, Inc. ("AbVacc") for the joint development of vaccine candidates targeting monkeypox and Marburg virus disease. In this effort, BWV and AbVacc will utilize BWV's VLP platform to present antigens from each disease to develop novel vaccine candidates, with the potential to expand this partnership to other disease areas of interest identified by BWV and AbVacc.
- To highlight its novel vaccine candidates, BWV management presented pipeline details and updates at several key scientific conferences throughout 2022 and into the first quarter of 2023, including the World Vaccine Congresses in Washington, D.C., Barcelona, and San Diego, as well as at the Universal Influenza Vaccines 2022 Conference in Oxford, and the Biotech Showcase during the 41st Annual JP Morgan Healthcare Conference
    - In addition to external events to highlight BWV's vaccine pipeline, BWV held its first Key Opinion Leader event in December 2022 to discuss the unmet need for an AOM and pneumococcal pneumonia vaccine. During the discussion, BWV-201 inventor Jason Rosch, Ph.D., and BWV consultant, Ali Fattom, Ph.D., presented the importance of mucosal immunity in vaccines and key data supporting BWV-201 as a solution for AOM and pneumococcal pneumonia.
- Throughout 2022, BWV expanded research and license agreements with esteemed collaborators to further advance vaccine candidates.
    - In May 2022, BWV announced an expanded license agreement with St. Jude Children's Research Hospital ("St. Jude"). Under this agreement, BWV will explore the potential to display additional pathogens capable of causing AOM, including non-typeable *Haemophilus influenzae* ("NTHi") and *Moraxella catarrhalis* ("*M. catarrhalis*"), on the surface of BWV-201, a live attenuated, serotype independent, intranasally delivered *Streptococcus pnuemoniae* ("*S. pneumoniae*") vaccine candidate. At the World Vaccine Congresses in Barcelona and San Diego, BWV presented data supporting this venture, showing that epitopes from these otopathogens were successfully displayed on the

surface of BWV-201 and mice vaccinated with the new construct were able to generate antibodies against NTHi, *M. catarrhalis*, and *S. pneumoniae*.

- In May 2022, BWV announced a collaboration with the multidisciplinary Center for R&D in Immunobiologics, an initiative of Instituto Butantan ("Butantan"). Through this partnership, BWV and Butantan will develop BWV's universal influenza vaccine candidate, BWV-101, in Brazil.
- In May 2022, BWV announced an expanded Sponsored Research Agreement with the University of Oxford to continue funding development of BWV's universal influenza vaccine candidate, BWV-101. This, along with the discovery of epitopes of limited variability in H3 influenza and influenza B, will allow BWV to progress BWV-101 through its preclinical development and reach clinical-stage.
- In July 2022, BWV signed a Sponsored Research Agreement with Cincinnati Children's to fund research into exploring the applicability of its VLP platform across multiple diseases, including rotavirus, norovirus, malaria, and influenza. Through further agreements and announcements, exploration of this platform has expanded to also include monkeypox and Marburg virus disease.

2022 Financial Highlights

- **Cash Position:** Cash was $25.8 million as of December 31, 2022, as compared to $1.9 million as of December 31, 2021. The increase was primarily due to the closing of BWV's initial public offering in February 2022, a private placement that closed on April 19, 2022, and a private placement that closed on August 11, 2022. The Company believes its cash and cash equivalents are sufficient to fund operations through at least the end of the third quarter of 2024.
- **Research and Development Expenses:** For the year ended December 31, 2022, research and development expenses increased by approximately $2.8 million compared to 2021. The increase was primarily attributable to an increase in employee compensation and benefits, an increase in preclinical development activities mainly related to BWV-201, and an increase in external research and development personnel costs, offset by a decrease in license fees.
- **General and Administrative Expenses:** For the year ended December 31, 2022, general and administrative expenses increased by approximately $7.3 million to $9.4 million from $2.1 million in 2021. The increase was mainly due to an increase in employee and director compensation and benefits, an increase in professional services related to being a public company and increases in various business activities related to company growth and development.
- **Other Income:** Other income of $61,410 for the year ended December 31, 2022 relates to the change in fair value of the contingent warrant liability, which was incurred at the close of the April and August Private Placements. There was no other income or expense during the year ended December 31, 2021.
- **Net Loss:** Net loss was approximately $13.4 million for the year ended December 31, 2022, as compared to $3.4 million for the year ended December 31, 2021. The increase is primarily due to research and development of preclinical vaccine candidate development, as well as an increase in G&A expenses associated with now being a public company.

BLUE WATER VACCINES INC.
Balance Sheets

	December 31,	December 31,

	2022	2021
ASSETS		
Current assets		
Cash	$ 25,752,659	$ 1,928,474
Prepaid expenses and other current assets	469,232	234,551
Deferred offering costs	—	757,646
Receivable from related parties	35,850	152,524
Total current assets	26,257,741	3,073,195
Prepaid expenses, long-term	38,617	—
Property and equipment, net	14,089	11,502
Total assets	**$ 26,310,447**	**$ 3,084,697**
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities		
Accounts payable	$ 1,499,296	$ 582,605
Accrued expenses	2,409,128	1,055,515
Contingent warrant liability	14,021	—
Total current liabilities	3,922,445	1,638,120
Total liabilities	**3,922,445**	**1,638,120**
Commitments and Contingencies		
Stockholders' equity		
Preferred stock, $0.00001 par value, 10,000,000 shares authorized at December 31, 2022 and 2021		
Series Seed: 0 and 1,150,000 shares designated at December 31, 2022 and 2021, respectively; 0 and 1,146,138 shares issued and outstanding at December 31, 2022 and 2021, respectively; $0 and $15.4 million aggregate liquidation preference at December 31, 2022 and 2021, respectively	—	11
Common stock, $0.00001 par value, 250,000,000 shares authorized at December 31, 2022 and 2021; 15,724,957 and 3,200,000 shares issued at December 31, 2022 and 2021, respectively; 15,265,228 and 3,200,000 shares outstanding at December 31, 2022 and 2021, respectively	157	32
Additional paid-in-capital	42,331,155	7,403,204
Treasury stock, at cost; 459,729 and 0 shares of common stock at December 31, 2022 and 2021, respectively	(566,810)	—
Accumulated deficit	(19,376,500)	(5,956,670)
Total stockholders' equity	22,388,002	1,446,577
Total liabilities and stockholders' equity	**$ 26,310,447**	**$ 3,084,697**

BLUE WATER VACCINES INC.
Statements of Operations

	Year Ended December 31, 2022	Year Ended December 31, 2021
Operating expenses		
General and administrative	$ 9,351,552	$ 2,092,304
Research and development	4,129,688	1,325,030
Total operating expenses	13,481,240	3,417,334
Loss from operations	(13,481,240)	(3,417,334)
Other income		
Change in fair value of contingent warrant liability	(61,410)	—
Total other income	(61,410)	—
Net loss	**$ (13,419,830)**	**$ (3,417,334)**
Cumulative preferred stock dividends	96,359	627,391
Net loss applicable to common stockholders	$ (13,516,189)	$ (4,044,725)
Net loss per share attributable to common stockholders, basic and diluted	$ (1.10)	$ (1.26)
Weighted average number of common shares outstanding, basic and diluted	12,271,449	3,200,000

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 at San Antonio ("UT Health"). 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, and prevention of pneumonia in older people at risk for contracting pneumococcal pneumonia, a significant unmet medical need. The advantage of this technology includes a serotype independent mucosal immunity that prevents colonization in the upper respiratory tract as well as systemic immunity that can confer serotype independent against invasive pneumococcal disease. The Company is also developing a *Chlamydia* vaccine candidate with UT Health 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 include, but are not limited to, statements concerning the Company's ability to implement its business strategy and operations, its cash needs, the development and efficacy of the Company's vaccine candidates, and the Company's anticipated future growth strategy. 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 Form 10-K , 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 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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