As filed with the Securities and Exchange Commission on April 28, 2023

Registration No. 333-267142

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

Post-Effective Amendment No. 1 to Form S-1 on Form S-3
REGISTRATION STATEMENT
UNDER
THE SECURITIES ACT OF 1933

Blue Water Biotech, Inc.

(Exact name of registrant as specified in its charter)

Delaware	2834	83-2262816
(State or jurisdiction of incorporation or organization)	(Primary Standard Industrial Classification Code Number)	(IRS Employer Identification No.)

201 E. Fifth Street, Suite 1900
Cincinnati, OH 45202
Telephone: (513) 620-4101
(Address, including zip code, and telephone number, including area code, of registrant's principal executive offices)

Joseph Hernandez
c/o Blue Water Biotech, Inc.
201 E. Fifth Street, Suite 1900
Cincinnati, Ohio 45202
Telephone: (513) 620-4101
(Name, address, including zip code, and telephone number, including area code, of agent for service)

Copies to:

Barry I. Grossman, Esq.
Jessica Yuan, Esq.
Ellenoff Grossman & Schole LLP
1345 Avenue of the Americas
New York, New York 10105
Phone: (212) 370-1300
Fax: (212) 370-7889

Approximate date of commencement of proposed sale to the public: As soon as practicable after the effective date of this registration statement.

If any of the securities being registered on this Form are to be offered on a delayed or continuous basis pursuant to Rule 415 under the Securities Act of 1933, check the following box. ☒

If this Form is filed to register additional securities for an offering pursuant to Rule 462(b) under the Securities Act, please check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering. ☐

If this Form is a post-effective amendment filed pursuant to Rule 462(c) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering. ☐

If this Form is a post-effective amendment filed pursuant to Rule 462(d) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering. ☐

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, or a smaller reporting company. See the definitions of "large accelerated filer," "accelerated filer" and "smaller reporting company" in Rule 12b-2 of the Exchange Act.

Large accelerated filer	☐	Accelerated filer	☐
Non-accelerated filer	☒	Smaller reporting company	☒
		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 to Section 7(a)(2)(B) of the Securities Act. ☐

Pursuant to Rule 429 under the Securities Act, the prospectus contained in this Post-Effective Amendment No. 1 to Form S-1 on Form S-3 Registration Statement (referred to herein as the Registration Statement) will be used as a combined prospectus in connection with this Registration Statement and (i) the Registration Statement on Form S-1 (File No. 333-267142) that was declared effective by the Securities and Exchange Commission on September 19, 2022; and (ii) the Registration Statement on Form S-1, as amended (File No. 333-264646), that was declared effective by the Securities and Exchange Commission on May 20, 2022. Accordingly, this Registration Statement also constitutes post-effective amendments to the registration statements identified in (i) through (ii) and such post-effective amendments will become effective concurrently with the effectiveness of this Registration Statement in accordance with Section 8(c) of the Securities Act.

The registrant hereby amends this Registration Statement on such date or dates as may be necessary to delay its effective date until the registrant shall file a further amendment which specifically states that this Registration Statement shall thereafter become effective in accordance with Section 8(a) of the Securities Act or until this Registration Statement shall become effective on such date as the Securities and Exchange Commission acting pursuant to said Section 8(a) may determine.

EXPLANATORY NOTE

Pursuant to Rule 429 under the Securities Act, the prospectus included in this Registration Statement is a combined prospectus relating to:

- The offer and resale of 70,849 shares of Common Stock ("April 2022 Wainwright Warrant Shares") issuable upon exercise of the warrants (the "April 2022 Wainwright Warrants") issued to H.C. Wainwright & Co., LLC, or its designees, in the April 2022 Private Placement, which were registered on a registration statement on Form S-1 (File No. 333-264646), that was declared effective by the SEC on May 20, 2022.

- The offer and resale of 220,997 shares of Common Stock ("August 2022 Wainwright Warrant Shares" and, together with the April 2022 Wainwright Warrant Shares, the "Wainwright Warrant Shares") issuable upon exercise of the warrants (the "August 2022 Wainwright Warrants" and, together with the April 2022 Wainwright Warrants, the "Wainwright Warrants") issued to H.C. Wainwright & Co., LLC, or its designees, in the August 2022 Private Placement, which were registered on a registration statement on Form S-1 (File No. 333-267142) that was declared effective by the SEC on September 19, 2022.

- The offer and resale of 4,972,428 shares of Common Stock ("Preferred Investment Option Shares," together with the Wainwright Warrant Shares, the "Warrant Shares") issuable upon exercise of the preferred investment options (the "Preferred Investment Options," together with the Wainwright Warrants, the "Warrants"), issued to the selling stockholders in the August 2022 Private Placement determined as if the outstanding Preferred Investment Options were exercised in full as of the trading day immediately preceding the date this registration statement was initially filed with the SEC, each as of the trading day immediately preceding the applicable date of determination and all subject to adjustment as provided in the registration right agreement, all of which were acquired by the selling stockholders in, which were registered on a registration statement on Form S-1 (File No. 333-267142) on September 19, 2022.

The information in this preliminary prospectus is not complete and may be changed. These securities may not be sold until the registration statement filed with the Securities and Exchange Commission is effective. This preliminary prospectus is not an offer to sell these securities and is not soliciting an offer to buy these securities in any state where the offer or sale is not permitted.

Subject to Completion, dated April 28, 2023

Prospectus

5,264,274 Shares of Common Stock

This prospectus relates to the offer and resale of up to an aggregate of 5,264,274 shares of Common Stock, par value $0.00001 per share ("Common Stock"), of Blue Water Biotech, Inc. (formerly known as Blue Water Vaccines Inc.) ("Blue Water," "BWV," "the Company," "we," "us" or "our") held by selling stockholders, consisting of:

- The offer and resale of 70,849 shares of Common Stock ("April 2022 Wainwright Warrant Shares") issuable upon exercise of the warrants (the "April 2022 Wainwright Warrants") issued to H.C. Wainwright & Co., LLC, or its designees, in the April 2022 Private Placement, which were registered on a registration statement on Form S-1 (File No. 333-264646), that was declared effective by the SEC on May 20, 2022.

- The offer and resale of 220,997 shares of Common Stock ("August 2022 Wainwright Warrant Shares" and, together with the April 2022 Wainwright Warrant Shares, the "Wainwright Warrant Shares") issuable upon exercise of the warrants (the "August 2022 Wainwright Warrants" and, together with the April 2022 Wainwright Warrant, the "Wainwright Warrants") issued to H.C. Wainwright & Co., LLC, or its designees, in the August 2022 Private Placement, which were registered on a registration statement on Form S-1 (File No. 333-267142) that was declared effective by the SEC on September 19, 2022.

- The offer and resale of 4,972,428 shares of Common Stock ("Preferred Investment Option Shares," together with the Wainwright Warrant Shares, the "Warrant Shares") issuable upon exercise of the preferred investment options (the "Preferred Investment Options," together with the Wainwright Warrants, the "Warrants"), issued to the selling stockholders in the August 2022 Private Placement determined as if the outstanding Preferred Investment Options were exercised in full as of the trading day immediately preceding the date this registration statement was initially filed with the SEC, each as of the trading day immediately preceding the applicable date of determination and all subject to adjustment as provided in the registration right agreement, all of which were acquired by the selling stockholders in, which were registered on a registration statement on Form S-1 (File No. 333-267142) on September 19, 2022.

The holders of the Warrant Shares and the Warrants are each referred herein as a "Selling Stockholder" and collectively as the "Selling Stockholders."

This prospectus also covers any additional shares of Common Stock that may become issuable upon any anti-dilution adjustment pursuant to the terms of the Warrants issued to the Selling Stockholders by reason of stock splits, stock dividends, and other events described therein.

The Selling Stockholders, or their respective transferees, pledgees, donees or other successors-in-interest, may sell the Warrant Shares through public or private transactions at prevailing market prices, at prices related to prevailing market prices or at privately negotiated prices. The Selling Stockholders may sell any, all or none of the securities offered by this prospectus, and we do not know when or in what amount the Selling Stockholders may sell their Warrant Shares hereunder following the effective date of this registration statement. We provide more information about how a Selling Stockholder may sell its Warrant Shares in the section titled "Plan of Distribution" on page 27.

We are registering the Warrant Shares on behalf of the Selling Stockholders, to be offered and sold by them from time to time. We will not receive any proceeds from the sale of our Common Stock by the Selling Stockholders in the offering described in this prospectus. We cannot predict when and in what amounts or if the Warrants will be exercised. We have agreed to bear all of the expenses incurred in connection with the registration of the Warrant Shares. The Selling Stockholders will pay or assume discounts, commissions, fees of underwriters, selling brokers or dealer managers and similar expenses, if any, incurred for the sale of the Warrant Shares.

We are an "emerging growth company" and a "smaller reporting company" as such terms are defined under federal securities laws, and, as such have elected to take advantage of certain reduced public company reporting requirements for this prospectus and may elect to do so in future filings.

This prospectus describes the general manner in which the Warrant Shares may be offered and sold. When the selling stockholders sell shares of Common Stock under this prospectus, we may, if necessary and required by law, provide a prospectus supplement that will contain specific information about the terms of that offering. Any prospectus supplement may also add to, update, modify or replace information contained in this prospectus. We urge you to read carefully this prospectus, any accompanying prospectus supplement and any documents we incorporate by reference into this prospectus and any accompanying prospectus supplement before you make your investment decision.

Our shares of Common Stock have experienced extreme volatility in market prices and trading volume since listing. From February 18, 2022 (the date our shares were initially listed on Nasdaq) to the date hereof, the market price of our Common Stock has fluctuated from an intra-day low on Nasdaq of $0.91 on November 9, 2022 to an intra-day high of $90.90 per share on February 22, 2022. By comparison, our initial public offering, which closed on February 23, 2022, was conducted at $9.00 per share. During this time, we have made various announcements regarding certain research developments and partnerships for our vaccine candidates. Notwithstanding the foregoing, since our initial public offering on February 18, 2022, there were no material recent publicly disclosed changes in the financial condition or results of operations of the Company, such as our earnings or revenue, that are consistent with or related to the changes in our stock price. The trading price of our Common Stock has been, and may continue to be, subject to wide price fluctuations in response to various factors, many of which are beyond our control, including those described under the heading “Risk Factors” beginning on page 7 of this prospectus.

Investing in our common stock is highly speculative and involves a significant degree of risk. See “Risk Factors” beginning on page 7 of this prospectus for a discussion of information that should be considered before making a decision to purchase our Common Stock.

Neither the Securities and Exchange Commission nor any state securities commission has approved or disapproved of these securities or determined if this prospectus is truthful or complete. Any representation to the contrary is a criminal offense.

The date of this prospectus is April 28, 2023.

TABLE OF CONTENTS

ABOUT THIS PROSPECTUS

We note that the representations, warranties and covenants made by us in any document that is filed as an exhibit to the registration statement of which this prospectus is a part and in any document that is incorporated by reference herein were made solely for the benefit of the parties to such agreement, including, in some cases, for the purpose of allocating risk among the parties to such agreements, and should not be deemed to be a representation, warranty or covenant to you. Moreover, such representations, warranties or covenants were accurate only as of the date when made. Accordingly, such representations, warranties and covenants should not be relied on as accurately representing the current state of our affairs.

Unless the context indicates otherwise, the terms “Blue Water,” “Company,” “we,” “us” and “our” refer to Blue Water Biotech, Inc. (formerly known as Blue Water Vaccines Inc.), a Delaware corporation.

PROSPECTUS SUMMARY

This summary highlights selected information contained elsewhere in this prospectus. This summary does not contain all the information that you should consider before investing in our Company. You should carefully read this entire prospectus, including all documents incorporated by reference. In particular, attention should be directed to our "Risk Factors" and the financial statements and related notes thereto contained herein or otherwise incorporated by reference hereto before making an investment decision.

Blue Water Biotech, Inc. is a biotechnology company focused on developing transformational therapies to address significant health challenges globally. We hold exclusive, global rights to novel technology licensed from renowned research institutions around the world, including St. Jude Children's Research Hospital, the University of Oxford, Cincinnati Children's Hospital Medical Center, and the University of Texas Health at San Antonio. We believe that our pipeline and vaccine platform are synergistic for developing next generation preventive vaccines to improve both health outcomes and quality of life globally. Outside of its vaccine franchise, Blue Water owns ENTADFI®, an FDA-approved, once daily pill that combines finasteride and tadalafil for the treatment of benign prostatic hyperplasia. This combination allows men to receive treatment for their symptoms of BPH without the negative sexual side effects typically seen in patients on finasteride alone.

Vaccine Programs

We seek to develop vaccines that provide long-lasting immunity to harmful viral and bacterial pathogens that cause infections in patient populations with high unmet needs. Our most advanced vaccine candidate is a live-attenuated, intranasally delivered, serotype independent *Streptococcus pneumoniae* vaccine to prevent middle ear infections, also known as acute otitis media ("AOM"), and pneumococcal pneumonia. AOM is a significant burden globally, particularly in young children, and pneumococcal pneumonia primarily impacts the elderly population. Additionally, we believe that this attenuated bacterium can serve as a platform to protect against other infectious agents that cause acute otitis media, such as non-typeable *Haemophilus influenzae* and *Moraxella catarrhalis*, by anchoring antigens from these pathogens on the surface of BWV-201, our attenuated *Streptococcus pneumoniae* bacterial vaccine. We hold a global, exclusive license to this technology, which was generated from the laboratory of Jason Rosch, Ph.D., of St. Jude Children's Research Hospital. Our influenza programs are based on technology developed by Sunetra Gupta, Ph.D. at the University of Oxford, for which we hold a global, exclusive license for use of epitopes of limited variability, ELVs, to develop novel influenza vaccine candidates. Identified through a proprietary computational research and discovery process, we believe a vaccine formulated with these epitopes from different influenza strains will produce a viable universal influenza vaccine candidate. We are exploring the development of these influenza ELVs utilizing our norovirus shell and protrusion ("S&P") nanoparticle vaccine platform, licensed from Cincinnati Children's Hospital Medical Center, or CHMC. We are also utilizing this platform to develop a vaccine for the prevention of gastroenteritis caused by norovirus or rotavirus, as well as novel vaccines for malaria and monkeypox. The final candidate in our vaccine pipeline is a live-attenuated, orally delivered vaccine to prevent Chlamydia, for which we have a global, exclusive license to this technology originated from the University of Texas Health at San Antonio. We leverage the expertise of each of our collaborators to pursue the discovery and development of vaccines for these diseases, each of which represent high unmet needs globally.

In addition, we have expertise in identifying business development opportunities for our platform vaccines technologies and portfolio. This allows for both internal pipeline expansion and the ability to generate non-dilutive revenue from potential licensing partners to utilize our discovery engine vaccine platform. There is potential for adjunctive or next generation therapeutic exploration to enhance current standard of care options.

Vaccination has been used as an effective method of protecting individuals against harmful diseases by utilizing the body's natural defense system to develop resistance or immunity to infections (World Health Organization, *https://www.who.int/news-room/q-a-detail/herd-immunity-lockdowns-and-covid-19*). The body's immune system naturally creates antibodies and cell -mediated immunity to defend against foreign pathogens. Vaccines introduce or present these foreign pathogens, prompting the body's immune system produce a response protective against the pathogen without exposing the body to the relevant lethal or harmful infection (World Health Organization, *https://www.who.int/news-room/q-a-detail/herd-immunity-lockdowns-and-covid-19*). While vaccines are generally able to provide resistance against disease, many infectious diseases can evolve or mutate leading to shortcomings of traditional vaccines, such as yearly reformulations. We believe our vaccine candidates can provide an alternative to the current standards of care by harnessing durable and long-lived immune response to specific or multiple antigens.

The global vaccine market has recently experienced significant growth caused by rising awareness of the importance of immunization and vaccination benefits in emerging markets as well as by projects to fuel further global market expansion. For instance, The World Health Organization ("WHO") has undertaken initiatives to increase immunization awareness through its Global Vaccine Action Plan and Global Immunization Vision and Strategy.

As such, market research professionals project the global vaccine market size to reach $73.78 billion by 2028, representing a CAGR of 7.3% over the forecast period, driven by rising prevalence of infectious diseases, increasing government funding for vaccine production and growing emphasis on becoming immunized.

This market acceleration has been coupled with various strategic transactions in the sector, including consolidations and mergers and acquisitions in recent years. Major market participants have strategically acquired start-ups and mid-sized companies to broaden their products portfolios and service offerings. For instance, in February 2019, Bharat Biotech acquired Chiron Behring Vaccines, one of the leading manufacturers of rabies vaccines across the globe. Additionally, in October 2018, Emergent BioSolutions, a multinational specialty biopharmaceutical company, acquired PaxVax for $270 million, and in July 2017 Sanofi acquired Protein Sciences for $650 million. In the pneumococcal disease market specifically, for which we are targeting for our *Streptococcus pneumoniae* vaccine candidate, GlaxoSmithKline acquired Affinivax for up to $3.3 billion in May 2022. The appetite of these companies to buttress their vaccine programs and pipelines reflects the increasing importance of vaccines in the healthcare sector, both nationally and worldwide.

The U.S. Centers for Disease Control and Prevention ("CDC"), its Advisory Committee on Immunization Practices ("ACIP"), and similar international advisory bodies develop vaccine recommendations for both children and adults. New pediatric vaccines that receive ACIP preferred recommendations are almost universally adopted, and adult vaccines that receive a preferred recommendation are widely adopted. We believe that our vaccine candidates will be well-positioned to obtain these preferred recommendations, by virtue of their longer and more durable immunity, which could drive rapid and significant market adoption.

Pipeline

Our vaccine candidates are being developed in a manner that is scalable, designed to be cost-effective and provide long-term benefit to patients from infectious agents.

The FDA regulatory approval process is lengthy and time-consuming, and we may experience significant delays in the clinical development and regulatory approval of our vaccine candidates. Our vaccine candidates are in early stages of development and may fail in development or suffer delays that materially and adversely affect their commercial viability. We may be unable to complete development of or commercialize our vaccine candidates or experience significant delays in doing so due to regulatory or other uncertainties.

Our Vaccine Candidates

BWV-201: Streptococcus pneumoniae (S. pneumoniae) vaccine program

We are developing BWV-201, licensed from St. Jude Children's Research Hospital, to prevent Acute Otitis Media, or AOM, in children and adults, a leading cause of hospital visits, prescription antibiotics and potentially permanent hearing loss. Based on information from the American Academy of Pediatrics, over 5 million cases of AOM are reported annually in the U.S., resulting in approximately 30 million medical care visits and over 10 million antibiotic prescriptions, representing approximately $4.3 billion spent on treatment in the U.S. alone. AOM due to *S. pneumoniae* infections range from 30 to 50% of all AOM infections each year (Monsata 2012 2012; 7(4): e36226). In addition to AOM, we are exploring the potential for BWV-201 to protect against non-invasive pneumococcal pneumonia, or colonization of the bacteria within the lungs that has not spread to the blood or other major organs. According to the CDC, pneumococcal pneumonia leads to an estimated 150,000 hospitalizations each year in the US alone (CDC Fast Facts: Pneumococcal Disease) and while there are commercially available pneumococcal vaccines, efficacy rates against pneumococcal pneumonia are low (Berild 2020; 9(4): 259) and vaccines are serotype independent (CDC: Pneumococcal Disease). BWV-201 is a live attenuated serotype-independent intranasal vaccine candidate for *S. pneumoniae* induced AOM and pneumococcal pneumonia.

BWV-101 and BWV-102: Influenza vaccine program

The company's influenza vaccine programs are focused on developing transformational and novel influenza vaccines: BWV-101 for an influenza vaccine to provide protection against H1, H3 and Flu B infections; and BWV-102 for a H1 only vaccine. This program is licensed from the University of Oxford in which all relevant studies were performed to support our hypothesis. Our goal is to develop a vaccine that protects against all influenza strains that commonly infect humans by targeting specific parts of the influenza viruses, which are of limited variability across flu strains and induce a strong protective immune response. This POC will be leveraged to develop BWV-101 by studying the cross-reactivity of different flu strains, H1, H3 and influenza B. The BWV-101 vaccine candidate may potentially provide a therapeutic benefit that negates the need for annual vaccination, vaccine reformulation, and provide long-lasting broad protection against the flu to millions globally (Thompson et al. Nature Communications. 2018. 9:385).

BWV Norovirus (NoV) S&P Nanoparticle Versatile vaccine platform

Our Approach to Stimulating the Immune System for Infectious Disease Protection

Our S&P platform was co-invented by two researchers, Xi Jason Jiang, Ph.D., and Ming Tan, Ph.D., of the Division of Infectious Disease at the Cincinnati Children's Hospital Medical Center. The pre-clinical research conducted at CHMC provided encouraging data that supports further investigation and development of the platform for our vaccine candidates. The S&P platform combines two or more immunogenic components, a norovirus antigen plus at least one additional antigen, together creating novel constructs. The norovirus nanoparticle enhances immunogenicity of the inserted antigen. The S&P particles themselves also act as antigens, and are large enough to trigger an immune response to a foreign substance. By combining the norovirus nanoparticle with one or more antigens from other infectious disease(s), the immune system is stimulated to create antibodies to both the norovirus and the additional antigen(s). Currently, we are evaluating this platform to generate vaccine candidates for norovirus, rotavirus, malaria, monkeypox, and Marburg virus disease.

Key Elements of our Platform

We are leveraging our disruptive norovirus nanoparticle platform to develop novel, broad-spectrum vaccines for adult and child infectious disease prevention by taking advantage of:

- Flexible and Scalable discovery platform engine. We believe we are able to design and create novel vaccines that are stable and scalable for broad spectrum prophylactics. Through this platform's adaptability, we may opportunistically expand our pipeline and potentially collaborate with third parties for additional vaccines, as well as therapeutics.

- Cost-effective and Rapid Production of Novel Vaccines. We are potentially able to reduce the cost and time to manufacture a vaccine candidate by utilizing an E.coli expression platform, compared to traditional vaccine production which uses other, longer production-time platforms, such as Chinese Hamster Ovary (CHO) cells. We have bioengineered these nanoparticles to be stable and effective, as determined through animal immunogenicity studies, using E.coli expression which may provide cost savings and efficiency compared to other VLPs needing a eukaryotic expression system. (Pharmaceutics 2019, 11, 472; doi:10.3390/pharmaceutics11090472).

- Multi-antigen and Pathogen Capabilities. One of the key features of our platform is its ability to carry multiple antigens at a time, thereby creating a multi-targeted vaccine. It also provides the opportunity to develop vaccines for protection against not only viral pathogens, but also bacterial and potentially parasitic and fungal pathogens.

- Therapeutic potential. We believe our platform may offer opportunities to develop non-infectious disease therapeutic products, for example being used as a carrier or vehicle to transport drugs to specific target locations.

BWV-401: Chlamydia vaccine program

We are developing a live attenuated, orally delivered chlamydia vaccine derived from a murine strain of chlamydia, *Chlamydia muridarum*, to protect individuals against chlamydia infection. By delivering this vaccine orally, BWV-401 may elicit transmucosal immunity and provide protection against chlamydia in the genital tract post-vaccination without altering the gut microbiota or the development of gut mucosal resident T cell responses to non-chlamydial infection. According to the CDC, there were about 1.6 million new cases of chlamydia reported in 2020 in the United States and globally, the WHO estimates about 129 million new cases each year. Additionally, given high estimations of asymptomatic cases and low availability of diagnostic testing in low- and middle-income countries, these annual estimates may be an underrepresentation. Currently, there is no vaccine available to prevent chlamydia infection, and the main treatment is through antibiotic regimens with the possibility of reinfection after antibiotics have treated the disease. If left undetected or untreated, Chlamydia represents a major cause of pelvic inflammatory disease and infertility in women. It is estimated that about 10 – 15% of women that experience untreaded chlamydia develop pelvic inflammatory disease and face chronic pain or fertility problems later in life. Additionally, should women contract chlamydia during pregnancy or give birth with an active infection, newborns may develop eye infections or pneumonia resulting from the disease. We believe this vaccine candidate has the potential to protect individuals against this harmful disease and may eliminate the need for antibiotic prescriptions associated with treating chlamydia.

BWV-301: Norovirus-rotavirus vaccine program

We are developing a norovirus-rotavirus vaccine, BWV-301, to prevent gastroenteritis utilizing our S&P platform. Preclinical data from gnotobiotic pig studies have shown our vaccine can prevent severe gastroenteritis and reduces viral shedding. While rotavirus vaccines exist in the market, no norovirus vaccine is available to date. Our vaccine would protect people from two of the most globally prevalent viruses causing vomiting and diarrhea.

BWV-302: Norovirus-malaria vaccine program

Additionally, we are currently investigating a malaria vaccine, BWV-302, utilizing our norovirus S&P platform. The vaccine is designed to offer protection from both norovirus and malaria, infectious diseases that occur frequently together in geographic regions. The vaccine utilizes a protein identified on the surface of the plasmodium parasite being presented on the surface of the norovirus nanoparticle.

Recent Developments

Entry into an At the Market Offering Agreement

On March 29, 2023, the Company entered into an At The Market Offering Agreement (the "Agreement") with H.C. Wainwright & Co., LLC, as sales agent (the "Agent"), to create an at-the-market equity program under which it may sell up to $3,900,000 of shares of the Company's common stock from time to time through the Agent (the "ATM Offering"). Under the Agreement, the Agent will be entitled to a commission at a fixed rate of 3.0% of the gross proceeds from each sale of shares of the Company's Common Stock under the Agreement.

Sales of the shares, if any, under the Agreement may be made in transactions that are deemed to be "at-the-market equity offerings" as defined in Rule 415 under the Securities Act of 1933, as amended, including sales made by means of ordinary brokers' transactions, including on the Nasdaq Capital Market, at prevailing market prices at the time of sale or as otherwise agreed with the Agent. The Company has no obligation to sell, and the Agent is not obligated to buy or sell, any of the shares under the Agreement and may at any time suspend offers under the Agreement or terminate the Agreement. The ATM Offering will terminate upon the termination of the Agreement as permitted therein.

The shares will be issued pursuant to the Company's previously filed Registration Statement on Form S-3 (File No. 333-270383) that was declared effective on March 16, 2023 and a prospectus supplement and accompanying prospectus relating to the ATM Offering filed with the with the Securities and Exchange Commission on March 29, 2023.

Purchase of ENTADFI®

On April 19, 2023, the Company entered into an Asset Purchase Agreement (the "Purchase Agreement") with Veru Inc., a Wisconsin corporation (the "Seller"). Pursuant to, and subject to the terms and conditions of, the Purchase Agreement, the Company purchased substantially all of the assets related to the Seller's ENTADFI® business ("ENTADFI®") and assumed certain liabilities of the Seller (the "Transaction"). The Transaction closed on April 19, 2023.

The Company purchased substantially all of the Seller's assets, rights and property related to ENTADFI® for a total possible consideration of $100,000,000 (as described below). The acquisition of ENTADFI® capitalizes on the demonstrable success of the FDA-approved drug ENTADFI® for treating benign prostatic hyperplasia and counteracting negative sexual side effects seen in men on alternative BPH therapies.

Furthermore, in connection with the Transaction, the Company assumed royalty and milestone obligations under an asset purchase agreement (the "APA") for tadalafil-finasteride combination entered into by the Seller and Camargo Pharmaceutical Services, LLC on December 11, 2017 (the "Camargo Obligations"). The Camargo Obligations assumed by the Company include a 6% royalty on all sales of tadalafil-finasteride and sales milestone payments of up to $22.5 million.

Pursuant to the terms of the APA, the Company provided the Seller with upfront consideration totaling $20,000,000, consisting of (i) $6.0 million paid upon the closing of the Transaction, (ii) an additional $4.0 million in the form of a non-interest bearing note payable due on September 30, 2023, and (iii) an additional $10 million in the form of two equal (i.e. each for $5 million) non-interest bearing notes payable, each due on April 19, 2024 and September 30, 2024.

Additionally, the terms of the Purchase Agreement require the Company to pay the Seller up to an additional $80 million based on the Company's net sales from the ENTADFI® business after closing (the "Milestone Payments"). The Milestone Payments are payable as follows: (i) $10 million is payable if the Company's annual net sales from the ENTADFI® business equal or exceed $100 million, (ii) $20 million is payable if the Company's annual net sales from the ENTADFI® business equal or exceed $200 million, and (3) $50 million is payable if annual net sales from the ENTADFI® business equal or exceed $500 million. No more than one Milestone Payment shall be made for the achievement of each net sales milestone. There can be no assurance that the net sales milestones for payment of any of the Milestone Payments will be reached.

Corporate Name Change

On April 21, 2023, the Company filed an amendment to its Second Amended and Restated Certificate of Incorporation with the Secretary of State of Delaware to change its corporate name from "Blue Water Vaccines Inc." to "Blue Water Biotech, Inc." The name change was effective as of April 21, 2023.

In connection with the name change, the Company amended the Company's bylaws to reflect the corporate name Blue Water Biotech, Inc., also effective on April 21, 2023. No other changes were made to the bylaws.

Implications of Being an Emerging Growth Company

We are an emerging growth company as defined in the Jumpstart Our Business Startups Act of 2012 (the "JOBS Act"). We may remain an "emerging growth company" until as late as December 31, 2027 (the fiscal year-end following the fifth anniversary of the completion of our initial public offering, which closed during February 2022), though we may cease to be an "emerging growth company" earlier under certain circumstances, including (1) if the market value of our Common Stock that is held by nonaffiliates exceeds $700 million as of any June 30, in which case we would cease to be an "emerging growth company" as of the following December 31, or (2) if our gross revenue exceeds $1.235 billion in any fiscal year. "Emerging growth companies" may take advantage of certain exemptions from various reporting requirements that are applicable to other public companies, including not being required to comply with the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act of 2002, reduced disclosure obligations regarding executive compensation in our periodic reports and proxy statements and exemptions from the requirements of holding a nonbinding advisory vote on executive compensation and stockholder approval of any golden parachute payments not previously approved. Investors could find our Common Stock less attractive because we may rely on these exemptions. If some investors find our Common Stock less attractive as a result, there may be a less active trading market for our Common Stock and our stock price may be more volatile.

In addition, Section 102 of the JOBS Act also provides that an "emerging growth company" can take advantage of the extended transition period provided in Section 7(a)(2)(B) of the Securities Act, for complying with new or revised accounting standards. An "emerging growth company" can therefore delay the adoption of certain accounting standards until those standards would otherwise apply to private companies.

Corporate Information

Our principal executive offices are located at 201 E. Fifth Street, Suite 1900, Cincinnati, OH 45202. Our telephone number is (513) 620-4101. Information about us is also available at our website at *http://www.bluewatervaccines.com*. The information on our website is not a part of, or incorporated in, this prospectus.

THE OFFERING

Common stock outstanding before this offering, as of April 15, 2023	15,924,070 shares.
Shares of Common Stock outstanding after completion of this offering (assuming full exercise of the Warrants that are exercisable for the Warrant Shares offered hereby):	21,188,344 shares.
Use of proceeds	We will not receive any proceeds from the sale of the Common Stock by the Selling Stockholders.
Transfer Agent	Continental Stock Transfer & Trust Company
Nasdaq Capital Market Symbol	"BWV"
Risk Factors	An investment in our Common Stock involves a high degree of risk. You should read this prospectus carefully, including the section titled "Risk Factors" and the financial statements and the related notes to those statements included in this prospectus, before investing in our Common Stock

Outstanding Shares of Common Stock

The number of shares of our Common Stock to be outstanding after this offering is based on 15,924,070 shares of Common Stock outstanding as of April 15, 2023, and excludes:

- 1,419,592 shares of Common Stock issuable upon the exercise of outstanding stock options under our 2019 Equity Incentive Plan, or the 2019 Plan, and 2022 Equity Incentive Plan, or the 2022 Plan, as of December 31, 2022;
- 969,036 shares of our Common Stock reserved for future issuance under our 2022 Plan;
- 5,264,274 shares of our Common Stock issuable upon the exercise of the Warrants;

Unless otherwise indicated, all information contained in this prospectus:

- assumes no exercise of the outstanding stock options described above; and
- assumes no exercise of the outstanding warrants described above.

RISK FACTORS

Investing in our securities is highly speculative and involves a high degree of risk. Before deciding whether to invest in our securities, you should carefully consider the risk factors we describe below, in any accompanying prospectus or any future prospectus supplement and in any related free writing prospectus for a specific offering of securities, as well as those incorporated by reference into this prospectus or such prospectus supplement. You should also carefully consider other information contained and incorporated by reference in this prospectus and any applicable prospectus supplement, including our financial statements and the related notes thereto incorporated by reference in this prospectus. The risks and uncertainties described herein and in the applicable prospectus supplement and our other filings with the SEC incorporated by reference herein are not the only ones we face. Additional risks and uncertainties not presently known to us or that we currently consider immaterial may also adversely affect us. If any of the described risks occur, our business, financial condition or results of operations could be materially harmed. In such case, the value of our securities could decline and you may lose all or part of your investment.

Summary

The risk factors described below are a summary of the principal risk factors associated with an investment in us. These are not the only risks we face. You should carefully consider these risk factors and the other reports and documents filed by us with the SEC.

- We are in the early stages of vaccine development and have a very limited operating history, which may make it difficult for you to evaluate the success of our business to date and to assess our future viability.
- We have incurred significant net losses since inception, do not generate any revenue, and anticipate that we will continue to incur substantial net losses for the foreseeable future and may never achieve profitability. Our stock is a highly speculative investment.
- We will require substantial additional funding to finance our operations. If we are unable to raise additional capital when needed, we could be forced to delay, reduce or terminate certain of our development programs or other operations.
- Raising additional capital may cause dilution to our existing stockholders and investors in this offering, restrict our operations or require us to relinquish rights to our product candidates on unfavorable terms to us.
- We have identified weaknesses in our internal controls, and we cannot provide assurances that these weaknesses will be effectively remediated or that additional material weaknesses will not occur in the future.
- We depend in part on the success of a limited number of product candidates, which are in preclinical development and none of which have commenced a clinical trial. If we do not obtain regulatory approval for and/or successfully commercialize one or more of our product candidates or we experience significant delays in doing so, we may never become profitable.
- We expect to rely on third party manufacturers for ENTADFI®.
- Disruptions to or significantly increased costs associated with transportation and other distribution channels for our products may adversely affect our margins and profitability.
- We may fail or elect not to commercialize ENTADFI®.
- We may not be able to gain and retain market acceptance for ENTADFI®.
- We may experience competition for ENTADFI®.

- We may not be able to successfully implement our strategy to grow sales of ENTADFI® in the U.S. market or, if authorized, any foreign market,
- We may engage in future acquisitions or strategic transactions which may require us to seek additional financing or financial commitments, increase our expenses and/or present significant distractions to our management.
- The market price of our Common Stock has been extremely volatile and may continue to be highly volatile due to numerous circumstances beyond our control, and stockholders could lose all or part of their investment.
- An active trading market for our Common Stock may not develop or be sustained.
- Our principal stockholders and management own a significant percentage of our capital stock and will be able to exert a controlling influence over our business affairs and matters submitted to stockholders for approval.
- There can be no assurance that we will be able to comply with the continued listing standards of Nasdaq.
- If our shares become subject to the penny stock rules, it would become more difficult to trade our shares.
- Future sales of our shares by existing stockholders could cause our stock price to decline.
- We are an “emerging growth company” and the reduced disclosure requirements applicable to emerging growth companies could make our Common Stock less attractive to investors.
- Our stock repurchase program may adversely affect our liquidity and cause fluctuations in our stock price.
- Our Amended and Restated Certificate of Incorporation and our Amended and Restated Bylaws and Delaware law may have anti-takeover effects that could discourage, delay or prevent a change in control, which may cause our stock price to decline.
- We do not anticipate paying any cash dividends on our Common Stock in the foreseeable future and, as such, capital appreciation, if any, of our Common Stock will be your sole source of gain for the foreseeable future.

We are in the early stages of vaccine development and have a very limited operating history, which may make it difficult for you to evaluate the success of our business to date and to assess our future viability.

To date, we have devoted substantially all of our resources to performing research and development, undertaking preclinical studies and enabling manufacturing activities in support of our product development efforts, hiring personnel, licensing and developing our technology and vaccine candidates, organizing and staffing our company, performing business planning, establishing our intellectual property portfolio and raising capital to support and expand such activities. As an organization, we have not yet demonstrated an ability to successfully complete clinical development, obtain regulatory approvals, manufacture a commercial-scale product or conduct sales and marketing activities necessary for successful commercialization or arrange for a third party to conduct these activities on our behalf. Consequently, any predictions about our future success or viability may not be as accurate as they could be if we had a longer operating history.

Our current vaccine candidate pipeline includes multiple preclinical programs. We may encounter unforeseen expenses, difficulties, complications, delays and other known or unknown factors in achieving our business objectives, including with respect to our vaccine candidates. We will need to transition in the future from a company with a research and development focus to a company capable of supporting commercial activities and may not be successful in such a transition.

We have incurred significant net losses since inception, do not generate any revenue, and anticipate that we will continue to incur substantial net losses for the foreseeable future and may never achieve profitability. Our stock is a highly speculative investment.

We are a preclinical stage biotechnology vaccine company that was incorporated in October 2018. Investment in preclinical stage companies and vaccine development is highly speculative because it entails substantial upfront capital expenditures and significant risk that any potential vaccine candidate will not gain regulatory approval or become commercially viable. We do not have any products approved for sale and have not generated any revenue from product sales. As a result, we are not profitable and have incurred losses in each year since inception. Our net loss was $13.4 million and $3.4 million for the years ended December 31, 2022 and 2021, respectively. As of December 31, 2022, we had an accumulated deficit of $19.4 million. We also generated negative operating cash flows of $8.7 million for the year ended December 31, 2022.

We expect to continue to spend significant resources to fund research and development of, and seek regulatory approvals for, our vaccine candidates. We expect to incur substantial and increasing operating losses over the next several years as our research, development, manufacturing, preclinical testing and clinical trial activities increase. As a result, our accumulated deficit will also increase significantly. Additionally, there can be no assurance that the product candidates currently under development or that may be under development by us in the future will be approved for sale in the U.S. or elsewhere. Furthermore, there can be no assurance that if such products are approved they will be successfully commercialized, and the extent of our future losses and the timing of our profitability are highly uncertain. If we are unable to achieve profitability, we may be unable to continue our operations.

We will require substantial additional funding to finance our operations. If we are unable to raise additional capital when needed, we could be forced to delay, reduce or terminate certain of our development programs or other operations.

As of December 31, 2022, we had cash of $25.8 million. As of December 31, 2021, we had cash of $1.9 million. On April 19, 2022, we closed the April Private Placement from which we received aggregate net proceeds of approximately $6.9 million, after deducting placement agent fees and other offering expenses. On August 11, 2022, we closed the August Private Placement from which we received approximately $8.7 million in net proceeds, after deducting placement agent fees and other offering expenses. In addition, in April 2023, the Company completed an acquisition of assets with a purchase price of $20.0 million, of which $6.0 million was paid upon close, and $9.0 million of the remainder is due to the seller of the assets within one year from the date of this Prospectus. We estimate that, based on our existing cash and our current obligations as of the date of this Prospectus, we will have cash on hand sufficient to fund our operations through the first quarter of 2024. Our ability to continue as a going concern beyond the first quarter of 2024 is contingent upon obtaining additional capital. We believe that we will need to raise substantial additional capital to fund our continuing operations beyond the first quarter of 2024, and the development and commercialization of our current product candidates and future product candidates in the long-term. We expect to finance our cash needs through public or private equity or debt financings, third-party (including government) funding and marketing and distribution arrangements, as well as other collaborations, strategic alliances and licensing arrangements or any combination of these approaches. In addition, we may need to accelerate the growth of our sales capabilities and distribution beyond what is currently envisioned, and this would require additional capital. In the event that we are unable to obtain additional financing, we may be unable to continue as a going concern. There is no guarantee that we will be able to secure additional financing, including in connection with this offering. Changes in our operating plans, our existing and anticipated working capital needs, costs related to legal proceedings we might become subject to in the future, the acceleration or modification of our development activities, any near-term or future expansion plans, increased expenses, potential acquisitions or other events may further affect our ability to continue as a going concern.

Our ability to raise additional capital may be adversely impacted by potential worsening global economic conditions and the recent disruptions to and volatility in the credit and financial markets in the United States and worldwide, including the trading price of Common Stock, resulting from the ongoing COVID-19 pandemic. Our future capital requirements will depend on many factors, including:

- the timing, scope, progress, results and costs of research and development, testing, screening, manufacturing, preclinical development and clinical trials;
- the outcome, timing and cost of seeking and obtaining regulatory approvals from the FDA and comparable foreign regulatory authorities, including the potential for such authorities to require that we perform field efficacy studies for our vaccine candidates, require more studies than those that we currently expect or change their requirements regarding the data required to support a marketing application;
- the cost of building a sales force in anticipation of any product commercialization;
- the costs of future commercialization activities, including product manufacturing, marketing, sales, royalties and distribution, for any of our vaccine candidates for which we receive marketing approval;
- our ability to maintain existing, and establish new, strategic collaborations, licensing or other arrangements and the financial terms of any such agreements, including the timing and amount of any future milestone, royalty or other payments due under any such agreement;
- any product liability or other lawsuits related to our products;
- the expenses needed to attract, hire and retain skilled personnel;
- the revenue, if any, received from commercial sales, or sales to foreign governments, of our vaccine candidates for which we may receive marketing approval;
- the costs to establish, maintain, expand, enforce and defend the scope of our intellectual property portfolio, including the amount and timing of any payments we may be required to make, or that we may receive, in connection with licensing, preparing, filing, prosecuting, defending and enforcing of any patents or other intellectual property rights;
- the expenses needed to attract, hire and retain skilled personnel;
- the costs of operating as a public company; and
- the impact of the COVID-19 pandemic or recent monkeypox outbreak, which may exacerbate the magnitude of the factors discussed above.

Our ability to raise additional funds will depend on financial, economic and other factors, many of which are beyond our control. We cannot be certain that additional funding will be available on acceptable terms, or at all. We have no committed source of additional capital and if we are unable to raise additional capital in sufficient amounts or on terms acceptable to us, we may have to significantly delay, scale back or discontinue the development or commercialization of our vaccine candidates or other research and development initiatives. Our license agreements may also be terminated if we are unable to meet the payment obligations or milestones under the agreements. We could be required to seek collaborators for our vaccine candidates at an earlier stage than otherwise would be desirable or on terms that are less favorable than might otherwise be available, or relinquish or license on unfavorable terms our rights to our vaccine candidates in markets where we otherwise would seek to pursue development or commercialization ourselves.

Raising additional capital may cause dilution to our existing stockholders and investors in this offering, restrict our operations or require us to relinquish rights to our product candidates on unfavorable terms to us.

We may seek additional capital through a variety of means, including through private and public equity offerings and debt financings, collaborations, strategic alliances and marketing, distribution or licensing arrangements. To the extent that we raise additional capital through the sale of equity or convertible debt securities, or through the issuance of shares under other types of contracts, or upon the exercise or conversion of outstanding options, warrants, convertible debt or other similar securities, the ownership interests of our stockholders will be diluted, and the terms of such financings may include liquidation or other preferences, anti-dilution rights, conversion and exercise price adjustments and other provisions that adversely affect the rights of our stockholders, including rights, preferences and privileges that are senior to those of our holders of Common Stock in terms of the payment of dividends or in the event of a liquidation. In addition, debt financing, if available, could include covenants limiting or restricting our ability to take certain actions, such as incurring additional debt, making capital expenditures, entering into licensing arrangements, or declaring dividends and may require us to grant security interests in our assets. If we raise additional funds through collaborations, strategic alliances, or marketing, distribution or licensing arrangements with third parties, we may have to relinquish valuable rights to our technologies, future revenue streams, product or product candidates or grant licenses on terms that may not be favorable to us. If we are unable to raise additional funds through equity or debt financings when needed, we may need to curtail or cease our operations.

We have identified weaknesses in our internal controls, and we cannot provide assurances that these weaknesses will be effectively remediated or that additional material weaknesses will not occur in the future.

As a public company, we are subject to the reporting requirements of the Exchange Act, and the Sarbanes-Oxley Act. We expect that the requirements of these rules and regulations will continue to increase our legal, accounting and financial compliance costs, make some activities more difficult, time consuming and costly, and place significant strain on our personnel, systems and resources.

The Sarbanes-Oxley Act requires, among other things, that we maintain effective disclosure controls and procedures, and internal control over financial reporting.

We do not yet have effective disclosure controls and procedures, or internal controls over all aspects of our financial reporting. We are continuing to develop and refine our disclosure controls and other procedures that are designed to ensure that information required to be disclosed by us in the reports that we will file with the SEC is recorded, processed, summarized and reported within the time periods specified in SEC rules and forms. Our management has deemed certain conditions to be material weaknesses in our internal controls. For example, we failed to employ a sufficient number of staff to maintain optimal segregation of duties and to provide optimal levels of oversight in order to process financial information in a timely manner, analyze and account for complex, non-routine transactions, and prepare financial statements. In addition, we do not yet have adequate internal controls in place for the timely identification, approval or reporting of related party transactions. Our management is responsible for establishing and maintaining adequate internal control over our financial reporting, as defined in Rule 13a-15(f) under the Exchange Act. We will be required to expend time and resources to further improve our internal controls over financial reporting, including by expanding our staff to include financial consultants and other qualified resources, which we commenced during the fourth quarter of 2021. However, we cannot assure you that our internal control over financial reporting, as modified, will enable us to identify or avoid material weaknesses in the future.

Our current controls and any new controls that we develop may become inadequate because of changes in conditions in our business, including increased complexity resulting from our international expansion. Further, weaknesses in our disclosure controls or our internal control over financial reporting may be discovered in the future. Any failure to develop or maintain effective controls, or any difficulties encountered in their implementation or improvement, could harm our operating results or cause us to fail to meet our reporting obligations and may result in a restatement of our financial statements for prior periods. Any failure to implement and maintain effective internal control over financial reporting could also adversely affect the results of management reports and independent registered public accounting firm audits of our internal control over financial reporting that we will eventually be required to include in our periodic reports that will be filed with the SEC. Ineffective disclosure controls and procedures, and internal control over financial reporting could also cause investors to lose confidence in our reported financial and other information, which would likely have a negative effect on the market price of our common stock.

We are required to comply with the SEC rules that implement Section 404 of the Sarbanes-Oxley Act, and are therefore required to make a formal assessment of the effectiveness of our internal control over financial reporting for that purpose. We are required to provide an annual management report on the effectiveness of our internal control over financial reporting in our annual report on Form 10-K. Our independent registered public accounting firm is not required to audit the effectiveness of our internal control over financial reporting until after we are no longer an “emerging growth company” as defined in the JOBS Act. At such time, our independent registered public accounting firm may issue a report that is adverse in the event it is not satisfied with the level at which our internal control over financial reporting is documented, designed or operating.

We depend in part on the success of a limited number of product candidates, which are in preclinical development and none of which have commenced a clinical trial. If we do not obtain regulatory approval for and/or successfully commercialize one or more of our product candidates or we experience significant delays in doing so, we may never become profitable.

We expect that a substantial portion of our efforts and expenses over the next few years will be devoted to the development of our product candidates; specifically, the commencement of Phase I clinical trials for our vaccine candidates. As a result, our business currently depends heavily on the successful development, regulatory approval and, if approved, commercialization of these product candidates. We cannot be certain that our product candidates will receive regulatory approval or will be successfully commercialized even if they receive regulatory approval. The research, testing, manufacturing, safety, efficacy, labeling, approval, sale, marketing and distribution of our product candidates are, and will remain, subject to comprehensive regulation by the FDA and similar foreign regulatory authorities. Before obtaining regulatory approvals for the commercial sale of any product candidate, we must demonstrate through pre-clinical studies and clinical trials that the product candidate is safe and effective for use in each target indication. Vaccine development is a long, expensive and uncertain process, and delay or failure can occur at any stage of any of our clinical trials. Failure to obtain regulatory approval for our product candidates in the United States will prevent us from commercializing and marketing our product candidates. The success of our product candidates will depend on several additional factors, including:

- completing clinical trials that demonstrate their efficacy and safety;
- receiving marketing approvals from applicable regulatory authorities;
- completing any post-marketing studies required by applicable regulatory authorities;
- establishing commercial manufacturing capabilities;
- launching commercial sales, marketing and distribution operations;
- the prevalence and severity of adverse events experienced with our product candidates;
- acceptance of our product candidates by patients, the medical community and third-party payors;
- a continued acceptable safety profile following approval;

- obtaining and maintaining healthcare coverage and adequate reimbursement for our product candidates;
- competing effectively with other therapies, including with respect to the sales and marketing of our product candidates, if approved; and
- qualifying for, maintaining, enforcing and defending our intellectual property rights and claims.

Many of these factors are beyond our control, including the time needed to adequately complete clinical testing, the regulatory submission process, potential threats to our intellectual property rights and changes in the competitive landscape. It is possible that none of our product candidates will ever obtain regulatory approval, even if we expend substantial time and resources seeking such approval. If we do not achieve one or more of these factors in a timely manner or at all, we could experience significant delays or an inability to successfully complete clinical trials, obtain regulatory approval or, if approved, commercialize our product candidates, which would materially harm our business, financial condition and results of operations.

We expect to rely on third party manufacturers for ENTADFI®.

For the foreseeable future, we expect to and do rely on third-party manufacturers and other third parties to produce, package and store sufficient quantities of ENTADFI® to meet demand. ENTADFI® is complicated and expensive to manufacture. If our third-party manufacturers fail to deliver ENTADFI® for clinical use on a timely basis, with sufficient quality, and at commercially reasonable prices, we may be required to delay or suspend clinical trials or otherwise discontinue development and production of ENTADFI®. While we may be able to identify replacement third-party manufacturers or develop our own manufacturing capabilities for ENTADFI®, this process would likely cause a delay in the availability of ENTADFI® and an increase in costs. In addition, third-party manufacturers may have a limited number of facilities in which ENTADFI® can be produced, and any interruption of the operation of those facilities due to events such as equipment malfunction or failure or damage to the facility by natural disasters could result in the cancellation of shipments, loss of product in the manufacturing process or a shortfall in ENTADFI®.

In addition, regulatory requirements could pose barriers to the manufacture of ENTADFI®. Third-party manufacturers are required to comply with the FDA's cGMPs. As a result, the facilities used by any manufacturers of ENTADFI® must maintain a compliance status acceptable to the FDA. Holders of NDAs, or other forms of FDA approvals or clearances, or those distributing a regulated product under their own name, are responsible for manufacturing even though that manufacturing is conducted by a third-party contract manufacturing organization ("CMO"). Our third-party manufacturers will be required to produce ENTADFI® under FDA cGMPs in order to meet acceptable standards. Our third-party manufacturers may not perform their obligations under their agreements with us or may discontinue their business before the time required by us to commercialize our drug candidates. In addition, our manufacturers will be subject to ongoing periodic unannounced inspections by the FDA and corresponding state and foreign agencies for compliance with cGMPs and similar regulatory requirements. Failure by any of our manufacturers to comply with applicable cGMPs could result in sanctions being imposed on us, including fines, injunctions, civil penalties, delays, suspensions or withdrawals of approvals, operating restrictions, interruptions in supply, recalls, withdrawals, issuance of safety alerts and criminal prosecutions, any of which could have a material adverse effect on our business, financial condition, results of operations and prospects. Finally, we also could experience manufacturing delays if our CMOs give greater priority to the supply of other products over ENTADFI® or otherwise do not satisfactorily perform according to the terms of their agreements with us.

If any supplier for ENTADFI® experiences any significant difficulties in its manufacturing processes, does not comply with the terms of the agreement between us or does not devote sufficient time, energy and care to providing our manufacturing needs, we could experience significant interruptions in the supply of ENTADFI®, which could impair our ability to supply ENTADFI® at the levels required for our clinical trials or commercialization and prevent or delay its successful development and commercialization.

Disruptions to or significantly increased costs associated with transportation and other distribution channels for ENTADFI® may adversely affect our margins and profitability.

We expect to rely on the uninterrupted and efficient operation of third-party logistics companies to transport and deliver ENTADFI®. These third-party logistics companies may experience disruptions to the transportation channels used to distribute our products, including disruptions caused by the COVID-19 pandemic, increased airport and shipping port congestion, a lack of transportation capacity, increased fuel expenses, and a shortage of manpower or capital or due to other business interruptions. Disruptions to the transportation channels experienced by our third-party logistics companies may result in increased costs, including the additional use of airfreight to meet demand. Disruptions to this business model or our relationship with the third party if, for example, performance fails to meet our expectations, could harm our business.

We may fail or elect not to commercialize ENTADFI®.

We may not successfully commercialize ENTADFI®. We or our collaboration partners in any potential commercial marketing efforts of ENTADFI may not be successful in achieving widespread patient or physician awareness or acceptance of this product. Also, we may be subject to pricing pressures from competitive products or from governmental or commercial payors or regulatory bodies that could make it difficult or impossible for us to commercialize ENTADFI® successfully. Any failure to commercialize ENTADFI® could have a material adverse effect on our future revenue and our business.

If we fail to commercialize ENTADFI®, our business, financial condition, results of operations and prospects may be materially adversely affected and our reputation in the industry and in the investment community would likely be damaged.

We may not be able to gain and retain market acceptance for ENTADFI®.

Physicians may not prescribe ENTADFI®, which would prevent ENTADFI® from generating revenue. Market acceptance of ENTADFI® by physicians, patients and payors, will depend on a number of factors, many of which are beyond our control, including the following:

- the clinical indications for which ENTADFI® is approved, if at all;
- acceptance by physicians and payors of ENTADFI® as safe and effective treatment;
- the cost of treatment in relation to alternative treatments;
- the relative convenience and ease of administration of ENTADFI® in the treatment of the conditions for which it is intended;
- the availability and efficacy of competitive drugs;
- the effectiveness of our sales and marketing efforts;
- the extent to which ENTADFI® is approved for inclusion on formularies of hospitals and managed care organizations;
- the availability of coverage and adequate reimbursement by third parties, such as insurance companies and other health care payors, or by government health care programs, including Medicare and Medicaid;
- limitations or warnings contained in a product's FDA or other applicable regulatory agency's approved labeling; and
- prevalence and severity of adverse side effects.

Even if the medical community accepts that ENTADFI® is safe and efficacious for its approved indications, physicians may not immediately be receptive to the use or may be slow to adopt such products as an accepted treatment for the conditions for which it is intended. Without head-to-head comparative data, we will also not be able to promote ENTADFI® as being superior to competing products. If ENTADFI® does not achieve an adequate level of acceptance by physicians and payors, we may not generate sufficient or any revenue from this products. In addition, our efforts to educate the medical community and third-party payors on the benefits of our product may require significant resources and may never be successful.

In addition, even if ENTADFI® achieve market acceptance, we may not be able to maintain that market acceptance over time if:

- new products or technologies are introduced that are more favorably received than ENTADFI®, are more cost effective or render ENTADFI® obsolete;
- unforeseen complications arise with respect to use of ENTADFI®; or
- sufficient third-party insurance coverage or reimbursement does not remain available.

We may experience competition for ENTADFI®.

We are engaged in the marketing of a product in industries, including the pharmaceutical industry, that are highly competitive. The pharmaceutical industry is also characterized by extensive research and rapid technological progress. Potential competitors with respect to ENTADFI® in North America, Europe and elsewhere include major pharmaceutical companies, specialty pharmaceutical companies and biotechnology firms, universities and other research institutions and government agencies. Many of our competitors have substantially greater research and development and regulatory capabilities and experience, and substantially greater management, manufacturing, distribution, marketing and financial resources, than we have. We may be unable to compete successfully against current and future competitors, and competitive pressures could have a negative effect on our net revenues and profit margins.

Other parties have developed and marketed drugs for BPH that have been accepted by the physician, patient and payor communities. Many of these other products have also reached the point where they are now generic drugs, which means that they are sold at a very low price, a price which ENTADFI® may not be able to meet which could limit ENTADFI®'s reach into the physician, patient and payor communities, including government payors.

We may not be able to successfully implement our strategy to grow sales of ENTADFI in the U.S. market or, if authorized, in any foreign market.

We may not be able to expand sales of ENTADFI® through partnering with telemedicine or other partners or through our own commercialization efforts. We may not be able to command a price with private and government payors for ENTADFI® that would justify our devotion of significant resources to attempting to grow sales of ENTADFI®. We may not be able to compete efficiently or effectively in a mature BPH market which is heavily generic. Failure to grow sales of ENTADFI® would have a negative effect on our revenue and future plans.

We may engage in future acquisitions or strategic transactions which may require us to seek additional financing or financial commitments, increase our expenses and/or present significant distractions to our management.

In the event we engage in an acquisition or strategic transaction, we may need to acquire additional financing (particularly, if the acquired entity is not cash flow positive or does not have significant cash on hand). Obtaining financing through the issuance or sale of additional equity and/or debt securities, if possible, may not be at favorable terms and may result in additional dilution to our current stockholders. Additionally, any such transaction may require us to incur non-recurring or other charges, may increase our near and long-term expenditures and may pose significant integration challenges or disrupt our management or business, which could adversely affect our operations and financial results. For example, an acquisition or strategic transaction may entail numerous operational and financial risks, including the risks outlined above and additionally:

- exposure to unknown liabilities;
- disruption of our business and diversion of our management's time and attention in order to develop acquired products or technologies;
- higher than expected acquisition and integration costs;
- write-downs of assets or goodwill or impairment charges;
- increased amortization expenses;
- difficulty and cost in combining the operations and personnel of any acquired businesses with our operations and personnel;
- impairment of relationships with key suppliers or customers of any acquired businesses due to changes in management and ownership; and
- inability to retain key employees of any acquired businesses.

Accordingly, although there can be no assurance that we will undertake or successfully complete any transactions of the nature described above, and any transactions that we do complete could have a material adverse effect on our business, results of operations, financial condition and prospects.

The market price of our Common Stock has been extremely volatile and may continue to be highly volatile due to numerous circumstances beyond our control, and stockholders could lose all or part of their investment.

The market price of our Common Stock may be highly volatile. Our stock price could be subject to wide fluctuations in response to a variety of factors, which include:

- whether we achieve our anticipated corporate objectives;
- actual or anticipated fluctuations in our financial condition and operating results;
- changes in financial or operational estimates or projections;
- the development status of our product candidates and when our products receive regulatory approval;
- our execution of our sales and marketing, manufacturing and other aspects of our business plan;
- performance of third parties on whom we rely to manufacture our products, product components and product candidates, including their ability to comply with regulatory requirements;
- the results of our clinical studies and clinical trials;

- results of operations that vary from those of our competitors and the expectations of securities analysts and investors;
- changes in expectations as to our future financial performance, including financial estimates by securities analysts and investors;
- our announcement of significant contracts, acquisitions or capital commitments;
- announcements by our competitors of competing products or other initiatives;
- announcements by third parties of significant claims or proceedings against us;
- regulatory and reimbursement developments in the United States and abroad;
- future sales of our Common Stock;
- product liability claims;
- healthcare reform measures in the United States;
- additions or departures of key personnel; and
- general economic or political conditions in the United States or elsewhere.

In addition, the stock market in general, and the stock of medical biotechnology companies like ours, in particular, have experienced extreme price and volume fluctuations that have often been unrelated or disproportionate to the operating performance of the issuer. For example, on March 15, 2022 and November 9, 2022, the closing price of our Common Stock on Nasdaq was $67.90 and $0.92, respectively, and daily trading volume on these days was approximately 12,500 and 236,500 shares, respectively. Additionally, our intraday trading prices have experienced extreme fluctuation. On April 7, 2022, the difference between our high and low trading price was $52.10. These broad market fluctuations may adversely affect the trading price of our Common Stock. In particular, a proportion of our Common Stock may be traded by short sellers which may put pressure on the supply and demand for our Common Stock, further influencing volatility in its market price. Additionally, these and other external factors have caused and may continue to cause the market price and demand for our Common Stock to fluctuate, which may limit or prevent investors from readily selling their shares of Common Stock and may otherwise negatively affect the liquidity of our Common Stock. While the market price of our Common Stock may respond to developments regarding operating performance and prospects, expansion plans, developments regarding our participation in direct contracting, the impacts of COVID-19, and developments regarding our industry, we believe that the extreme volatility we experienced in recent periods reflects market and trading dynamics unrelated to our underlying business, our actual or expected operating performance, our financial condition, or macro or industry fundamentals, and we do not know if these dynamics will continue or how long they will last . Under these circumstances, we caution you against investing in our Common Stock, unless you are prepared to incur the risk of losing all or a substantial portion of your investment.

An active trading market for our Common Stock may not develop or be sustained.

Prior to the commencement of trading of our Common Stock on February 18, 2022, no public market for our Common Stock existed. Although our Common Stock is listed on The Nasdaq Capital Market, an active trading market for our Common Stock may not develop, or if developed, be sustained. The lack of an active market may impair your ability to sell your shares at the time you wish to sell them or at a price that you consider reasonable. The lack of an active market may also reduce the fair value of your shares.

Further, an inactive market may also impair our ability to raise capital by selling shares of our Common Stock may impair our ability to enter into strategic partnerships or acquire companies or products by using our shares of Common Stock as consideration.

Our principal stockholders and management own a significant percentage of our capital stock and will be able to exert a controlling influence over our business affairs and matters submitted to stockholders for approval.

As of April 15, 2023, our officers and directors, together with holders of 5% or more of our outstanding Common Stock and their respective affiliates, beneficially own or control 7,260,172 shares of our Common Stock, which in the aggregate represents approximately 45.6% of the outstanding shares of our Common Stock. As a result, if some of these persons or entities act together, they will have the ability to exercise significant influence over matters submitted to our stockholders for approval, including the election and removal of directors, amendments to our Amended and Restated Certificate of Incorporation and Amended and Restated Bylaws, the approval of any business combination and any other significant corporate transaction. These actions may be taken even if they are opposed by other stockholders. This concentration of ownership may also have the effect of delaying or preventing a change of control of our company or discouraging others from making tender offers for our shares, which could prevent our stockholders from receiving a premium for their shares. Some of these persons or entities who make up our principal stockholders may have interests different from yours.

There can be no assurance that we will be able to comply with the continued listing standards of Nasdaq.

Our continued eligibility for listing on Nasdaq depends on our ability to comply with Nasdaq's continued listing requirements. If Nasdaq delists the Common Stock from trading on its exchange for failure to meet the listing standards, we and our stockholders could face significant material adverse consequences including:

- a limited availability of market quotations for our securities;
- a determination that our Common Stock is a "penny stock," which will require brokers trading in our Common Stock to adhere to more stringent rules, possibly resulting in a reduced level of trading activity in the secondary trading market for our Common Stock;
- a limited amount of analyst coverage; and
- a decreased ability to issue additional securities or obtain additional financing in the future.

If our shares become subject to the penny stock rules, it would become more difficult to trade our shares.

The SEC has adopted rules that regulate broker-dealer practices in connection with transactions in penny stocks. Penny stocks are generally equity securities with a price of less than $5.00, other than securities registered on certain national securities exchanges or authorized for quotation on certain automated quotation systems, provided that current price and volume information with respect to transactions in such securities is provided by the exchange or system. If we do not retain a listing on Nasdaq and if the price of our Common Stock is less than $5.00, our Common Stock will be deemed a penny stock. The penny stock rules require a broker-dealer, before a transaction in a penny stock not otherwise exempt from those rules, to deliver a standardized risk disclosure document containing specified information. In addition, the penny stock rules require that before effecting any transaction in a penny stock not otherwise exempt from those rules, a broker-dealer must make a special written determination that the penny stock is a suitable investment for the purchaser and receive (i) the purchaser's written acknowledgment of the receipt of a risk disclosure statement; (ii) a written agreement to transactions involving penny stocks; and (iii) a signed and dated copy of a written suitability statement. These disclosure requirements may have the effect of reducing the trading activity in the secondary market for our Common Stock, and therefore stockholders may have difficulty selling their shares.

Future sales of our shares by existing stockholders could cause our stock price to decline.

If we or our existing stockholders, directors and officers sell, or indicate an intent to sell, substantial amounts of our Common Stock or securities convertible into our Common Stock in the public market after contractual lock-up and other legal restrictions on resale discussed in this prospectus lapse, the trading price of our Common Stock could decline significantly and could decline below the initial public offering price. We have outstanding 15,924,070 shares of Common Stock as of the date hereof, assuming no exercise of outstanding options or warrants, are or will be freely tradable, without restriction, in the public market. If our existing stockholders sell substantial amounts of our Common Stock in the public market, or if the public perceives that such sales could occur, this could have an adverse impact on the market price of our Common Stock, even if there is no relationship between such sales and the performance of our business. We also intend to register all shares of Common Stock that we may issue under our equity compensation plan. Once we register these shares, they can be freely sold in the public market upon issuance, subject to volume limitations applicable to affiliates and lock-up agreements.

Upon issuance, the 1,419,592 shares subject to outstanding options under our stock option plan and the shares reserved for future issuance under our stock option plan will become eligible for sale in the public market in the future, subject to certain legal and contractual limitations. If our existing stockholders sell substantial amounts of our Common Stock in the public market, or if the public perceives that such sales could occur, this could have an adverse impact on the market price of our Common Stock, even if there is no relationship between such sales and the performance of our business.

We are an "emerging growth company" and the reduced disclosure requirements applicable to emerging growth companies could make our Common Stock less attractive to investors.

We are an "emerging growth company," as defined in the JOBS Act. We may remain an "emerging growth company" until as late as December 31, 2027 (the fiscal year-end following the fifth anniversary of the completion of our initial public offering, which closed in February 2022), though we may cease to be an "emerging growth company" earlier under certain circumstances, including (1) if the market value of our Common Stock that is held by nonaffiliates exceeds $700 million as of any June 30, in which case we would cease to be an "emerging growth company" as of the following December 31, or (2) if our gross revenue exceeds $1.235 billion in any fiscal year. "Emerging growth companies" may take advantage of certain exemptions from various reporting requirements that are applicable to other public companies, including not being required to comply with the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act, reduced disclosure obligations regarding executive compensation in our periodic reports and proxy statements and exemptions from the requirements of holding a nonbinding advisory vote on executive compensation and stockholder approval of any golden parachute payments not previously approved. Investors could find our Common Stock less attractive because we may rely on these exemptions. If some investors find our Common Stock less attractive as a result, there may be a less active trading market for our Common Stock and our stock price may be more volatile.

In addition, Section 102 of the JOBS Act also provides that an "emerging growth company" can take advantage of the extended transition period provided in Section 7(a)(2)(B) of the Securities Act, for complying with new or revised accounting standards. An "emerging growth company" can therefore delay the adoption of certain accounting standards until those standards would otherwise apply to private companies.

Our stock repurchase program may adversely affect our liquidity and cause fluctuations in our stock price.

On November 8, 2022, our Board authorized a stock repurchase program pursuant to which the Company may repurchase up to 5 million shares of our Common Stock, with a maximum price of $1.00 per share, with discretion to management to make purchases subject to market conditions. On November 18, 2022, our Board approved an increase to the maximum price to $2.00 per share.

Potential future stock repurchases under the stock share repurchase program could be funded by operating cash flow or excess cash balances. The maximum number of shares of the Company's Common Stock that may yet be repurchased under the share repurchase program is 4.5 million. Repurchases under the stock repurchase program may adversely affect our liquidity, which in turn could impact our profitability, financial condition and results of operations. In addition, repurchases under the stock repurchase program will reduce the number of shares of our Common Stock available for purchase and sale in the public market, which could affect the market price of our Common Stock. Furthermore, the Inflation Reduction Act of 2022, which was signed into law in August 2022, imposes a non-deductible 1% excise tax on the fair market value of stock repurchases after December 31, 2022 that exceed $1.0 million in a taxable year, which may impact the tax efficiency of our stock repurchase program.

Our Amended and Restated Certificate of Incorporation and our Amended and Restated Bylaws and Delaware law may have anti-takeover effects that could discourage, delay or prevent a change in control, which may cause our stock price to decline.

Our Amended and Restated Certificate of Incorporation and our Amended and Restated Bylaws and Delaware law could make it more difficult for a third party to acquire us, even if closing such a transaction would be beneficial to our stockholders. Our Amended and Restated Certificate of Incorporation authorizes us to issue up to 10,000,000 shares of preferred stock. This preferred stock may be issued in one or more series, the terms of which may be determined at the time of issuance by our board of directors without further action by stockholders. The terms of any series of preferred stock may include voting rights (including the right to vote as a series on particular matters), preferences as to dividend, liquidation, conversion and redemption rights and sinking fund provisions. The issuance of any preferred stock could materially adversely affect the rights of the holders of our Common Stock, and therefore, reduce the value of our Common Stock. In particular, specific rights granted to future holders of preferred stock could be used to restrict our ability to merge with, or sell our assets to, a third party and thereby preserve control by the present management.

Provisions of our Amended and Restated Certificate of Incorporation, our Amended and Restated Bylaws and Delaware law also could have the effect of discouraging potential acquisition proposals or making a tender offer or delaying or preventing a change in control, including changes a stockholder might consider favorable. Such provisions may also prevent or frustrate attempts by our stockholders to replace or remove our management. In particular, our Amended and Restated Certificate of Incorporation, our Amended and Restated Bylaws and Delaware law, as applicable, among other things:

- provide the board of directors with the ability to alter the bylaws without stockholder approval;
- place limitations on the removal of directors;
- establish advance notice requirements for nominations for election to the board of directors or for proposing matters that can be acted upon at stockholder meetings; and
- provide that vacancies on the board of directors may be filled by a majority of directors in office, although less than a quorum.

These provisions, alone or together, could delay or prevent hostile takeovers and changes in control or changes in our management.

As a Delaware corporation, we are also subject to provisions of Delaware law, including Section 203 of the Delaware General Corporation law, which prevents certain stockholders holding more than 15% of our outstanding capital stock from engaging in certain business combinations without approval of the holders of at least two-thirds of our outstanding Common Stock not held by such stockholder.

Any provision of our Amended and Restated Certificate of Incorporation, Amended and Restated Bylaws or Delaware law that has the effect of delaying, preventing or deterring a change in control could limit the opportunity for our stockholders to receive a premium for their shares of our capital stock, and could also affect the price that some investors are willing to pay for our Common Stock.

We do not anticipate paying any cash dividends on our Common Stock in the foreseeable future and, as such, capital appreciation, if any, of our Common Stock will be your sole source of gain for the foreseeable future.

We have never declared or paid cash dividends on our Common Stock. We do not anticipate paying any cash dividends on our Common Stock in the foreseeable future. We currently intend to retain all available funds and any future earnings to fund the development and growth of our business. In addition, and any future loan arrangements we enter into may contain, terms prohibiting or limiting the amount of dividends that may be declared or paid on our Common Stock. As a result, capital appreciation, if any, of our Common Stock, which may never occur, will be your sole source of gain for the foreseeable future.

CAUTIONARY NOTE REGARDING FORWARD-LOOKING STATEMENTS AND INDUSTRY AND MARKET DATA

Special Note Regarding Forward-Looking Statements

This prospectus contains forward-looking statements that involve substantial risks and uncertainties. The forward-looking statements are contained principally in the sections titled "Prospectus Summary" and "Risk Factors," but are also contained elsewhere in this prospectus. In some cases, you can identify forward-looking statements by the words "may," "might," "will," "could," "would," "should," "expect," "intend," "plan," "objective," "anticipate," "believe," "estimate," "predict," "project," "potential," "continue" and "ongoing," or the negative of these terms, or other comparable terminology intended to identify statements about the future, although not all forward-looking statements contain these words. These statements relate to future events or our future financial performance or condition and involve known and unknown risks, uncertainties and other factors that could cause our actual results, levels of activity, performance or achievement to differ materially from those expressed or implied by these forward-looking statements. These forward-looking statements include, but are not limited to, statements about:

- our projected financial position and estimated cash burn rate;
- our estimates regarding expenses, future revenues and capital requirements;
- our ability to continue as a going concern;
- our need to raise substantial additional capital to fund our operation;
- the success, cost and timing of our clinical trials;
- our dependence on third parties in the conduct of our clinical trials;
- our ability to obtain the necessary regulatory approvals to market and commercialize our product candidates;
- the ultimate impact of the ongoing COVID-19 pandemic, or any other health epidemic, on our business, our clinical trials, our research programs, healthcare systems or the global economy as a whole;
- the potential that results of pre-clinical and clinical trials indicate our current product candidates or any future product candidates we may seek to develop are unsafe or ineffective;
- the results of market research conducted by us or others;
- our ability to obtain and maintain intellectual property protection for our current product candidates;
- our ability to protect our intellectual property rights and the potential for us to incur substantial costs from lawsuits to enforce or protect our intellectual property rights;
- the possibility that a third party may claim we or our third-party licensors have infringed, misappropriated or otherwise violated their intellectual property rights and that we may incur substantial costs and be required to devote substantial time defending against claims against us;
- our reliance on third parties;
- the success of competing therapies and products that are or become available;
- our ability to expand our organization to accommodate potential growth and our ability to retain and attract key personnel;
- the potential for us to incur substantial costs resulting from product liability lawsuits against us and the potential for these product liability lawsuits to cause us to limit our commercialization of our product candidates;
- market acceptance of our product candidates, the size and growth of the potential markets for our current product candidates and any future product candidates we may seek to develop, and our ability to serve those markets; and
- the successful development of our commercialization capabilities, including sales and marketing capabilities.

These forward-looking statements are subject to a number of risks, uncertainties and assumptions, including those described in “Risk Factors” and those discussed in other documents that we filed with SEC. The following discussion should be read in conjunction with the financial statements for the fiscal years ended December 31, 2021 and December 31, 2022, and notes incorporated by reference herein. Moreover, we operate in a very competitive and rapidly changing environment. New risks emerge from time to time. It is not possible for our management to predict all risks, nor can we assess the impact of all factors on our business or the extent to which any factor, or combination of factors, may cause actual results to differ materially from those contained in any forward-looking statements we may make. In light of these risks, uncertainties and assumptions, the forward-looking events and circumstances discussed in this prospectus and the documents incorporated by reference herein may not occur and actual results could differ materially and adversely from those anticipated or implied in the forward-looking statements.

You should not rely upon forward-looking statements as predictions of future events. Although we believe that the expectations reflected in the forward-looking statements are reasonable, we cannot guarantee that the future results, levels of activity, performance or events and circumstances reflected in the forward-looking statements will be achieved or occur. Moreover, except as required by law, neither we nor any other person assumes responsibility for the accuracy and completeness of the forward-looking statements. We undertake no obligation to update publicly any forward-looking statements for any reason after the date of this prospectus to conform these statements to actual results or to changes in our expectations.

You should read this prospectus and the documents that we reference in this prospectus and have filed with the SEC, including any exhibits thereto, with the understanding that our actual future results, levels of activity, performance and events and circumstances may be materially different from what we expect.

Industry and Market Data

This prospectus contains industry, market and competitive position data from our own internal estimates and research as well as independent industry publications, general publications and research surveys and studies conducted by third parties. This data involves a number of assumptions and limitations, and while we believe that the data from these industry publications that is included in this prospectus is reliable, we have not independently verified the data from third-party sources. In addition, while we believe that the results and estimates from our internal research are reliable, such results and estimates have not been verified by any independent source. The industry in which we operate is subject to a high degree of uncertainty and risk due to a variety of factors, including those described in “Risk Factors” and elsewhere in this prospectus. These and other factors could cause results to differ materially from those expressed in the estimates made by the independent parties and by us.

USE OF PROCEEDS

We will not receive any proceeds from the sale of the Common Stock by the selling stockholders. We may receive proceeds upon the exercise of the warrants for which shares of Common Stock are registered hereunder (to the extent the registration statement of which this prospectus is a part is then effective and, if applicable, the "cashless exercise" provision is not utilized by the holder). Any proceeds will be used for general corporate and working capital or for other purposes that the Board of Directors, in their good faith, deems to be in the best interest of the Company. No assurances can be given that any of such warrants will be exercised.

DETERMINATION OF OFFERING PRICE

The selling stockholders will offer Common Stock at the prevailing market prices or privately negotiated price.

The offering price of our Common Stock does not necessarily bear any relationship to our book value, assets, past operating results, financial condition or any other established criteria of value. The facts considered in determining the offering price were our financial condition and prospects, our limited operating history and the general condition of the securities market.

In addition, there is no assurance that our Common Stock will trade at market prices in excess of the offering price as prices for Common Stock in any public market will be determined in the marketplace and may be influenced by many factors, including the depth and liquidity.

DIVIDEND POLICY

We have never paid or declared any cash dividends on our Common Stock, and we do not anticipate paying any cash dividends on our Common Stock in the foreseeable future. We intend to retain all available funds and any future earnings to fund the development and expansion of our business. Any future determination to pay dividends will be at the discretion of our board of directors and will depend upon a number of factors, including our results of operations, financial condition, future prospects, contractual restrictions, restrictions imposed by applicable law and other factors our board of directors deems relevant. Our future ability to pay cash dividends on our stock may also be limited by the terms of any future debt or preferred securities or future credit facility.

DESCRIPTION OF SECURITIES TO BE REGISTERED

The following is a summary of the rights of our Common Stock, certain provisions of our Amended and Restated Certificate of Incorporation and our Amended and Restated Bylaws and applicable law. This summary does not purport to be complete and is qualified in its entirety by the provisions of our Amended and Restated Certificate of Incorporation and our Amended and Restated Bylaws, copies of which have been filed as exhibits to the registration statement and are incorporated by reference to our registration statement, of which this prospectus forms a part.

Authorized Capital Stock

As of the date of this prospectus, our authorized capital stock consists of 250,000,000 shares of Common Stock, par value $0.00001 per share and 10,000,000 shares of preferred stock, par value $0.00001 per share. Our authorized but unissued shares of Common Stock and preferred stock are available for issuance without further action by our stockholders, unless such action is required by applicable law or the rules of any stock exchange or automated quotation system on which our securities may be listed or traded in the future.

Common Stock

As of the date of this prospectus, there were 16,417,517 and 15,924,070 shares of Common Stock issued (including treasury shares acquired by us through repurchases) and outstanding, 5,264,274 shares of Common Stock issuable upon exercise of outstanding warrants, and 1,419,592 shares of Common Stock issuable upon exercise of outstanding stock options.

Under the terms of our Amended and Restated Certificate of Incorporation, holders of our Common Stock are entitled to one vote for each share held on all matters submitted to a vote of stockholders, including the election of directors, and do not have cumulative voting rights. The holders of outstanding shares of Common Stock are entitled to receive dividends out of assets or funds legally available for the payment of dividends of such times and in such amounts as our board of directors from time to time may determine. Our Common Stock is not entitled to pre-emptive rights and is not subject to conversion or redemption. Upon liquidation, dissolution or winding up of our company, the assets legally available for distribution to stockholders are distributable ratably among the holders of our Common Stock after payment of liquidation preferences, if any, on any outstanding payment of other claims of creditors. The rights, preferences and privileges of holders of Common Stock are subject to and may be adversely affected by the rights of the holders of shares of any series of preferred stock that we may designate and issue in the future.

Anti-Takeover Provisions of Delaware Law and Our Amended and Restated Certificate of Incorporation and Amended and Restated Bylaws

Section 203 of the Delaware General Corporation Law

We are subject to Section 203 of the DGCL, which prohibits a Delaware corporation from engaging in any business combination with any interested stockholder for a period of three years after the date that such stockholder became an interested stockholder, with the following exceptions:

- before such date, the board of directors of the corporation approved either the business combination or the transaction that resulted in the stockholder becoming an interested stockholder;
- upon completion of the transaction that resulted in the stockholder becoming an interested stockholder, the interested stockholder owned at least 85% of the voting stock of the corporation outstanding at the time the transaction began, excluding for purposes of determining the voting stock outstanding (but not the outstanding voting stock owned by the interested stockholder) those shares owned (i) by persons who are directors and also officers and (ii) employee stock plans in which employee participants do not have the right to determine confidentially whether shares held subject to the plan will be tendered in a tender or exchange offer; or
- on or after such date, the business combination is approved by the board of directors and authorized at an annual or special meeting of the stockholders, and not by written consent, by the affirmative vote of at least 66⅔% of the outstanding voting stock that is not owned by the interested stockholder.

Section 203 defines a "business combination" to include the following:

- any merger or consolidation involving the corporation and the interested stockholder;
- any sale, transfer, pledge or other disposition of 10% or more of the assets of the corporation involving the interested stockholder;
- subject to certain exceptions, any transaction that results in the issuance or transfer by the corporation of any stock of the corporation to the interested stockholder;
- any transaction involving the corporation that has the effect of increasing the proportionate share of the stock or any class or series of the corporation beneficially owned by the interested stockholder; and
- the receipt by the interested stockholder of the benefit of any loans, advances, guarantees, pledges or other financial benefits by or through the corporation.

In general, Section 203 defines an "interested stockholder" as an entity or person who, together with the person's affiliates and associates, beneficially owns, or within three years prior to the time of determination of interested stockholder status did own, 15% or more of the outstanding voting stock of the corporation.

The statute could prohibit or delay mergers or other takeover or change in control attempts and, accordingly, may discourage attempts to acquire us even though such a transaction may offer our stockholders the opportunity to sell their stock at a price above the prevailing market price.

Amended and Restated Certificate of Incorporation and Amended and Restated Bylaws

Among other things, our Amended and Restated Certificate of Incorporation and our Amended and Restated Bylaws:

- permit our board of directors to issue up to 10,000,000 shares of preferred stock, with any rights, preferences and privileges as they may designate, including the right to approve an acquisition or other change in control;
- provide that the authorized number of directors may be changed only by resolution of our board of directors;
- provide that our board of directors will be classified into three classes of directors;
- provide that, subject to the rights of any series of preferred stock to elect directors, directors may only be removed for cause, which removal may be effected, subject to any limitation imposed by law, by the holders of at least 66⅔% of the voting power of all of our then-outstanding shares of the capital stock entitled to vote generally at an election of directors;
- provide that all vacancies, including newly created directorships, may, except as otherwise required by law, be filled by the affirmative vote of a majority of directors then in office, even if less than a quorum;
- require that any action to be taken by our stockholders must be effected at a duly called annual or special meeting of stockholders and not be taken by written consent or electronic transmission;
- provide that stockholders seeking to present proposals before a meeting of stockholders or to nominate candidates for election as directors at a meeting of stockholders must provide advance notice in writing, and also specify requirements as to the form and content of a stockholder's notice;

- provide that special meetings of our stockholders may be called only by the chairman of our board of directors, our chief executive officer or president or by our board of directors pursuant to a resolution adopted by a majority of the total number of authorized directors, and not by our stockholders; and

- not provide for cumulative voting rights, therefore allowing the holders of a majority of the shares of Common Stock entitled to vote in any election of directors to elect all of the directors standing for election, if they should so choose.

The amendment of any of these provisions would require approval by the holders of at least 66⅔% of the voting power of all of our then-outstanding Common Stock entitled to vote generally in the election of directors, voting together as a single class.

The combination of these provisions will make it more difficult for our existing stockholders to replace our board of directors as well as for another party to obtain control of us by replacing our board of directors. Because our board of directors has the power to retain and discharge our officers, these provisions could also make it more difficult for existing stockholders or another party to effect a change in management. In addition, the authorization of undesignated preferred stock makes it possible for our board of directors to issue preferred stock with voting or other rights or preferences that could impede the success of any attempt to change our control.

These provisions are intended to enhance the likelihood of continued stability in the composition of our board of directors and its policies and to discourage coercive takeover practices and inadequate takeover bids. These provisions are also designed to reduce our vulnerability to hostile takeovers and to discourage certain tactics that may be used in proxy fights. However, such provisions could have the effect of discouraging others from making tender offers for our shares and may have the effect of delaying changes in our control or management. As a consequence, these provisions may also inhibit fluctuations in the market price of our stock that could result from actual or rumored takeover attempts. We believe that the benefits of these provisions, including increased protection of our potential ability to negotiate with the proponent of an unfriendly or unsolicited proposal to acquire or restructure our company, outweigh the disadvantages of discouraging takeover proposals, because negotiation of takeover proposals could result in an improvement of their terms.

Choice of Forum

Our Amended and Restated Certificate of Incorporation requires, to the fullest extent permitted by law, that derivative actions brought in our name, actions against directors, officers and employees for breach of fiduciary duty and certain other actions may be brought only in the Court of Chancery in the State of Delaware, except any action (A) as to which the Court of Chancery in the State of Delaware determines that there is an indispensable party not subject to the jurisdiction of the Court of Chancery (and the indispensable party does not consent to the personal jurisdiction of the Court of Chancery within ten days following such determination), (B) which is vested in the exclusive jurisdiction of a court or forum other than the Court of Chancery or (C) for which the Court of Chancery does not have subject matter jurisdiction. If an action is brought outside of Delaware, the stockholder bringing the suit will be deemed to have consented to service of process on such stockholder's counsel. Although we believe this provision benefits us by providing increased consistency in the application of law in the types of lawsuits to which it applies, a court may determine that this provision is unenforceable, and to the extent it is enforceable, the provision may have the effect of discouraging lawsuits against our directors and officers.

Our Amended and Restated Certificate of Incorporation provides that the exclusive forum provision will be applicable to the fullest extent permitted by applicable law, subject to certain exceptions. Section 27 of the Exchange Act creates exclusive federal jurisdiction over all suits brought to enforce any duty or liability created by the Exchange Act or the rules and regulations thereunder. As a result, the exclusive forum provision will not apply to suits brought to enforce any duty or liability created by the Exchange Act or any other claim for which the federal courts have exclusive jurisdiction. In addition, our Amended and Restated Certificate of Incorporation provides that, unless we consent in writing to the selection of an alternative forum, the federal district courts of the United States of America shall, to the fullest extent permitted by law, be the exclusive forum for the resolution of any complaint asserting a cause of action arising under the Securities Act or the rules and regulations promulgated thereunder. We note, however, that there is uncertainty as to whether a court would enforce this provision and that investors cannot waive compliance with the federal securities laws and the rules and regulations thereunder. Section 22 of the Securities Act creates concurrent jurisdiction for state and federal courts over all suits brought to enforce any duty or liability created by the Securities Act or the rules and regulations thereunder.

Limitation on Liability and Indemnification

See the section titled "Management — Limitation on Liability and Indemnification Matters."

Listing

Our Common Stock is listed on The Nasdaq Capital Market under the trading symbol "BWV."

Transfer Agent and Registrar

The transfer agent and registrar for our Common Stock is Continental Stock Transfer & Trust Company. The Transfer Agent's address is 1 State Street, 30th Floor, New York, New York 10004.

SELLING STOCKHOLDERS

The Warrant Shares being offered by the Selling Stockholders are those previously issued to the selling shareholders in the Private Placements, and those issuable to the selling stockholders, upon exercise of the Preferred Investment Options and the Wainwright Warrants. We are registering the Warrant Shares in order to permit the selling stockholders to offer the shares for resale from time to time. Except for the ownership of shares of Common Stock and the Preferred Investment Options and Wainwright Warrants, the selling stockholders have not had any material relationship with us within the past three years; *provided, however,* each of Michael Vasinkevich, Noam Rubinstein, Craig Schwabe and Charles Worthman are associated persons of Wainwright, which served as our placement agent in connection with the Private Placements for which Wainwright received compensation.

The table below lists the Selling Stockholders and other information regarding the beneficial ownership of the shares of Common Stock by each of the Selling Stockholders. The second column lists the number of shares of Common Stock beneficially owned by each selling stockholder, based on its ownership of the shares of Common Stock and Warrants, as of April 15, 2023, assuming exercise of the Warrants held by the Selling Stockholders on that date, without regard to any limitations on exercises.

The fourth column lists the Warrant Shares being offered by this prospectus by the Selling Stockholders.

In accordance with the terms of a registration rights agreement with the Selling Stockholders, this prospectus generally covers the resale of the sum of (i) the number of shares of Common Stock issued to the Selling Stockholders and (ii) the maximum number of shares of Common Stock issuable upon exercise of the related warrants, determined as if the outstanding warrants were exercised in full as of the trading day immediately preceding the date this Registration Statement was initially filed with the SEC, each as of the trading day immediately preceding the applicable date of determination and all subject to adjustment as provided in the registration right agreement, without regard to any limitations on the exercise of the Warrants. The fifth column assumes the sale of all of the shares offered by the Selling Stockholders pursuant to this prospectus.

The table is based on information supplied to us by the Selling Stockholders, with beneficial ownership and percentage ownership determined in accordance with the rules and regulations of the SEC and includes voting or investment power with respect to shares of Common Stock. This information does not necessarily indicate beneficial ownership for any other purpose. In computing the number of shares of Common Stock beneficially owned by a Selling Stockholder and the percentage ownership of that Selling Stockholder, shares of Common Stock subject to warrants held by that Selling Stockholder that are exercisable for shares of Common Stock within 60 days after April 15, 2023, are deemed outstanding. Such shares, however, are not deemed outstanding for the purposes of computing the percentage ownership of any other stockholder.

Under the terms of the Warrants, a selling stockholder may not exercise the Warrants to the extent such exercise would cause such selling stockholders, together with its affiliates and attribution parties, to beneficially own a number of shares of Common Stock which would exceed 4.99% or 9.99%, as applicable, of our then outstanding Common Stock following such exercise, excluding for purposes of such determination shares of Common Stock issuable upon exercise of such Warrants which have not been exercised. The number of shares in the second and fourth columns do not reflect this limitation. The selling stockholders may sell all, some or none of their shares in this offering. See “Plan of Distribution.”

Name of Selling Shareholder	Number of shares of Common Stock Beneficially Owned Prior to Offering[1]	Maximum Number of Placement Shares to be Sold Pursuant to this Prospectus[2]	Maximum Number of Warrant Shares to be Sold Pursuant to this Prospectus[3]	Number of shares of Common Stock Owned After Offering[4]	Percentage Beneficially Owned After Offering[4]
Sabby Volatility Warrant Master Fund, Ltd.[5]	2,486,214[6]	0	2,486,214[6]	—	—
Armistice Capital Master Fund Ltd.[7]	2,468,214[8]	0	2,486,214[8]	—	—
Michael Vasinkevich[9]	187,146	0	187,146	—	—
Noam Rubinstein[9]	91,932	0	91,932	—	—
Craig Schwabe[9]	9,850	0	9,850	—	—
Charles Worthman[9]	2,918	0	2,918	—	—

(1) All of the Warrants that are exercisable for the Warrant Shares offered hereby contain certain beneficial ownership limitations, which provide that a holder of the Warrants will not have the right to exercise any portion of its Warrants if such holder, together with its affiliates and attribution parties, would beneficially own in excess of 4.99% or 9.99%, as applicable, of the number of shares of Common Stock outstanding immediately after giving effect to such exercise, provided that upon at least 61 days’ prior notice to us, a holder may increase or decrease such limitation up to a maximum of 9.99% of the number of shares of Common Stock outstanding (each such limitation, a “Beneficial Ownership Limitation”).

(2) Represents shares of Common Stock issued to the Selling Stockholders in the Private Placement and offered hereby.

(3) Represents shares of Common Stock owned by the Selling Stockholders upon full exercise of the Warrants offered hereby.

(4) We do not know when or in what amounts a Selling Stockholder may offer shares for sale. The Selling Stockholders might not sell any or might sell all of the shares offered by this prospectus. Because the Selling Stockholders may offer all or some of the shares pursuant to this offering, and because there are currently no agreements, arrangements or understandings with respect to the sale of any of the shares, we cannot estimate the number of the shares that will be held by the Selling Stockholders after completion of the offering. However, for purposes of this table, we have assumed that, after completion of the offering, none of the shares covered by this prospectus will be held by the Selling Stockholders, including Common Stock issuable upon exercise of the Warrants issued in the Private Placement.

(5) Sabby Management, LLC is the investment manager of Sabby Volatility Warrant Master Fund, Ltd. and shares voting and investment power with respect to these shares in this capacity. As manager of Sabby Management, LLC, Hal Mintz also shares voting and investment power on behalf of Sabby Volatility Warrant Master Fund, Ltd. Each of Sabby Management, LLC and Hal Mintz disclaims beneficial ownership over the securities listed except to the extent of their pecuniary interest therein.

(6) Includes the 1,428,916 Warrants that are not presently exercisable as a result of the 4.99% Beneficial Ownership Limitation.

(7) The securities reported herein are held by Armistice Capital Master Fund Ltd., a Cayman Islands exempted company (the "Master Fund"), and may be deemed to be indirectly beneficially owned by: (i) Armistice Capital, LLC ("Armistice Capital"), as the investment manager of the Master Fund; and (ii) Steven Boyd, as the Managing Member of Armistice Capital. Armistice Capital and Steven Boyd disclaim beneficial ownership of the securities except to the extent of their respective pecuniary interests therein. The address of the Master Fund is c/o Armistice Capital, LLC, 510 Madison Ave, 7th Floor, New York, NY 10022.

(8) Includes the 369,498 Warrants that are not presently exercisable as a result of the 9.99% Beneficial Ownership Limitation.

(9) Each of the Selling Stockholder is affiliated with H.C. Wainwright & Co., LLC, a registered broker dealer, and has a registered address of c/o H.C. Wainwright & Co., LLC, 430 Park Ave, 3rd Floor, New York, NY 10022. The Selling Stockholder purchased the Warrants in the ordinary course of business and, at the time of purchase of the securities that are registered for resale, the selling stockholders had no agreements or understanding, directly or indirectly with any person to distribute securities.

PLAN OF DISTRIBUTION

Each Selling Stockholder (the "Selling Stockholders") of the securities and any of their pledgees, assignees and successors-in-interest may, from time to time, sell any or all of their securities covered hereby on the Nasdaq Capital Market or any other stock exchange, market or trading facility on which the securities are traded or in private transactions. These sales may be at fixed or negotiated prices. A Selling Stockholder may use any one or more of the following methods when selling securities:

- ordinary brokerage transactions and transactions in which the broker-dealer solicits purchasers;
- block trades in which the broker-dealer will attempt to sell the securities as agent but may position and resell a portion of the block as principal to facilitate the transaction;
- purchases by a broker-dealer as principal and resale by the broker-dealer for its account;
- an exchange distribution in accordance with the rules of the applicable exchange;
- privately negotiated transactions;
- settlement of short sales;
- in transactions through broker-dealers that agree with the Selling Stockholders to sell a specified number of such securities at a stipulated price per security;
- through the writing or settlement of options or other hedging transactions, whether through an options exchange or otherwise;
- a combination of any such methods of sale; or
- any other method permitted pursuant to applicable law.

The Selling Stockholders may also sell securities under Rule 144 or any other exemption from registration under the Securities Act of 1933, as amended (the "Securities Act"), if available, rather than under this prospectus.

Broker-dealers engaged by the Selling Stockholders may arrange for other brokers-dealers to participate in sales. Broker-dealers may receive commissions or discounts from the Selling Stockholders (or, if any broker-dealer acts as agent for the purchaser of securities, from the purchaser) in amounts to be negotiated, but, except as set forth in a supplement to this Prospectus, in the case of an agency transaction not in excess of a customary brokerage commission in compliance with FINRA Rule 2121; and in the case of a principal transaction a markup or markdown in compliance with FINRA Rule 2121.

In connection with the sale of the securities or interests therein, the Selling Stockholders may enter into hedging transactions with broker-dealers or other financial institutions, which may in turn engage in short sales of the securities in the course of hedging the positions they assume. The Selling Stockholders may also sell securities short and deliver these securities to close out their short positions, or loan or pledge the securities to broker-dealers that in turn may sell these securities. The Selling Stockholders may also enter into option or other transactions with broker-dealers or other financial institutions or create one or more derivative securities which require the delivery to such broker-dealer or other financial institution of securities offered by this prospectus, which securities such broker-dealer or other financial institution may resell pursuant to this prospectus (as supplemented or amended to reflect such transaction).

The Selling Stockholders and any broker-dealers or agents that are involved in selling the securities may be deemed to be "underwriters" within the meaning of the Securities Act in connection with such sales. In such event, any commissions received by such broker-dealers or agents and any profit on the resale of the securities purchased by them may be deemed to be underwriting commissions or discounts under the Securities Act. Each Selling Stockholder has informed the Company that it does not have any written or oral agreement or understanding, directly or indirectly, with any person to distribute the securities.

The Company is required to pay certain fees and expenses incurred by the Company incident to the registration of the securities. The Company has agreed to indemnify the Selling Stockholders against certain losses, claims, damages and liabilities, including liabilities under the Securities Act.

We agreed to keep this prospectus effective until the earlier of (i) the date on which the securities may be resold by the Selling Stockholders without registration and without regard to any volume or manner-of-sale limitations by reason of Rule 144, without the requirement for the Company to be in compliance with the current public information under Rule 144 under the Securities Act or any other rule of similar effect or (ii) all of the securities have been sold pursuant to this prospectus or Rule 144 under the Securities Act or any other rule of similar effect. The resale securities will be sold only through registered or licensed brokers or dealers if required under applicable state securities laws. In addition, in certain states, the resale securities covered hereby may not be sold unless they have been registered or qualified for sale in the applicable state or an exemption from the registration or qualification requirement is available and is complied with.

Under applicable rules and regulations under the Exchange Act, any person engaged in the distribution of the resale securities may not simultaneously engage in market making activities with respect to the Common Stock for the applicable restricted period, as defined in Regulation M, prior to the commencement of the distribution. In addition, the Selling Stockholders will be subject to applicable provisions of the Exchange Act and the rules and regulations thereunder, including Regulation M, which may limit the timing of purchases and sales of the Common Stock by the Selling Stockholders or any other person. We will make copies of this prospectus available to the Selling Stockholders and have informed them of the need to deliver a copy of this prospectus to each purchaser at or prior to the time of the sale (including by compliance with Rule 172 under the Securities Act).

LEGAL MATTERS

Ellenoff Grossman & Schole LLP, New York, New York, is acting as counsel in connection with the registration of our securities under the Securities Act, and as such, will pass upon the validity of the securities offered in this prospectus.

EXPERTS

The financial statements of Blue Water Biotech, Inc. (formerly known as Blue Water Vaccines Inc.) as of and for the years ended December 31, 2022 and 2021, included in our Annual Report on Form 10-K for the year ended December 31, 2022, have been audited by Mayer Hoffman McCann P.C., independent registered public accounting firm, as set forth in their report, and have been incorporated herein by reference in reliance upon such report given on the authority of such firm as experts in auditing and accounting.

WHERE YOU CAN FIND MORE INFORMATION

We have filed with the SEC a registration statement on Form S-3 under the Securities Act with respect to the Common Stock offered in this prospectus. This prospectus, which constitutes a part of the registration statement, does not contain all of the information set forth in the registration statement and its exhibits and schedules, portions of which have been omitted as permitted by the rules and regulations of the SEC. For further information about us and our Common Stock, we refer you to the registration statement and to its exhibits and schedules. Statements in this prospectus about the contents of any contract, agreement or other document are not necessarily complete and, in each instance, we refer you to the copy of such contract, agreement or document filed as an exhibit to the registration statement, with each such statement being qualified in all respects by reference to the document to which it refers. Anyone may inspect and copy the registration statement and its exhibits and schedules at the Public Reference Room the SEC maintains at 100 F Street, N.E., Washington, D.C. 20549. You may obtain further information about the operation of the SEC's Public Reference Room by calling the SEC at 1-800-SEC-0330. You may also inspect the registration statement and its exhibits and schedules and other information without charge at the website maintained by the SEC. The address of this site is *www.sec.gov*.

We also file periodic reports, proxy statements and other information with the SEC. These reports, proxy statements and other information will be available for inspection and copying at the public reference room and website of the SEC referred to above. We also maintain a website at *www.bluewaterrvaccines.com*, by which you may access these materials free of charge as soon as reasonably practicable after they are electronically filed with, or furnished to, the SEC. The information that is contained on, or that may be accessed through, our website is not a part of this prospectus. We have included our website in this prospectus solely as an inactive textual reference.

You should rely only on the information contained in this prospectus. We have not authorized any person to provide you with any information that is different.

INCORPORATION OF DOCUMENTS BY REFERENCE

We are "incorporating by reference" in this prospectus certain documents we file with the SEC, which means that we can disclose important information to you by referring you to those documents. The information in the documents incorporated by reference is considered to be part of this prospectus. Statements contained in documents that we file with the SEC and that are incorporated by reference in this prospectus will automatically update and supersede information contained in this prospectus, including information in previously filed documents or reports that have been incorporated by reference in this prospectus, to the extent the new information differs from or is inconsistent with the old information. We have filed or may file the following documents with the SEC and they are incorporated herein by reference as of their respective dates of filing.

1. Our Annual Report on Form 10-K for the year ended December 31, 2022 as filed with the SEC on March 9, 2023; and

2. Our Current Reports on Form 8-K as filed with the SEC on January 17, 2023; February 16, 2023; March 29, 2023; April 20, 2023; and April 24, 2023.

All documents that we filed with the SEC pursuant to Sections 13(a), 13(c), 14, and 15(d) of the Exchange Act subsequent to the date of this registration statement and prior to the filing of a post-effective amendment to this registration statement that indicates that all securities offered under this prospectus have been sold, or that deregisters all securities then remaining unsold, will be deemed to be incorporated in this registration statement by reference and to be a part hereof from the date of filing of such documents.

Any statement contained in a document incorporated or deemed to be incorporated by reference in this prospectus shall be deemed modified, superseded or replaced for purposes of this prospectus to the extent that a statement contained in this prospectus, or in any subsequently filed document that also is deemed to be incorporated by reference in this prospectus, modifies, supersedes or replaces such statement. Any statement so modified, superseded or replaced shall not be deemed, except as so modified, superseded or replaced, to constitute a part of this prospectus. None of the information that we disclose under Items 2.02 or 7.01 of any Current Report on Form 8-K or any corresponding information, either furnished under Item 9.01 or included as an exhibit therein, that we may from time to time furnish to the SEC will be incorporated by reference into, or otherwise included in, this prospectus, except as otherwise expressly set forth in the relevant document. Subject to the foregoing, all information appearing in this prospectus is qualified in its entirety by the information appearing in the documents incorporated by reference.

You may request, orally or in writing, a copy of these documents, which will be provided to you at no cost (other than exhibits, unless such exhibits are specifically incorporate by reference), by contacting the Chief Financial Officer, at Blue Water Biotech, Inc., 2041 Courtland Avenue, Cincinnati, OH 45212, or by telephone at (646) 303-0737. Information about us is also available at our website at www.bluewatervaccines.com. However, the information in our website is not a part of this prospectus and is not incorporated by reference.

You should rely only on the information contained in this document. We have not authorized anyone to provide you with information that is different. This document may only be used where it is legal to sell these securities. The information in this document may only be accurate on the date of this document.

Additional risks and uncertainties not presently known or that are currently deemed immaterial may also impair our business operations. The risks and uncertainties described in this document and other risks and uncertainties which we may face in the future will have a greater impact on those who purchase our Common Stock. These purchasers will purchase our Common Stock at the market price or at a privately negotiated price and will run the risk of losing their entire investment.

5,264,274 Shares of Common Stock

PROSPECTUS

April 28, 2023

PART II

INFORMATION NOT REQUIRED IN PROSPECTUS

ITEM 14. OTHER EXPENSES OF ISSUANCE AND DISTRIBUTION

The following table sets forth the expenses in connection with this registration statement. All of such expenses are estimates, other than the filing fees payable to the Securities and Exchange Commission.

Description	Amount to be Paid
Filing Fee - Securities and Exchange Commission	$ 1,554.48**
Attorney's fees and expenses	25,000*
Accountant's fees and expenses	30,000*
Total	$ 56,554.48*

* Estimated

** Previously paid

ITEM 15. INDEMNIFICATION OF DIRECTORS AND OFFICERS

As permitted by Section 102 of the Delaware General Corporation Law, provisions in our Amended and Restated Certificate of Incorporation and our Amended and Restated Bylaws limit or eliminate the personal liability of our directors for a breach of their fiduciary duty of care as a director. The duty of care generally requires that, when acting on behalf of the corporation, directors exercise an informed business judgment based on all material information reasonably available to them. Consequently, a director will not be personally liable to us or our stockholders for monetary damages for breach of fiduciary duty as a director, except for liability for:

- any breach of the director's duty of loyalty to us or our stockholders;
- any act or omission not in good faith or that involves intentional misconduct or a knowing violation of law;
- any act related to unlawful stock repurchases, redemptions or other distributions or payment of dividends; or
- any transaction from which the director derived an improper personal benefit.

These limitations of liability do not affect the availability of equitable remedies such as injunctive relief or rescission. Our Amended and Restated Certificate of Incorporation also authorizes us to indemnify our officers, directors and other agents to the fullest extent permitted under Delaware law.

As permitted by Section 145 of the Delaware General Corporation Law, our Amended and Restated Bylaws provide that:

- we may indemnify our directors, officers and employees to the fullest extent permitted by the Delaware General Corporation Law, subject to limited exceptions;
- we may advance expenses to our directors, officers and employees in connection with a legal proceeding to the fullest extent permitted by the Delaware General Corporation Law, subject to limited exceptions; and
- the rights provided in our bylaws are not exclusive.

Our Amended and Restated Certificate of Incorporation and our Amended and Restated Bylaws provide for the indemnification provisions described above and elsewhere herein. We have entered or will enter into, and intend to continue to enter into, separate indemnification agreements with our directors and officers that may be broader than the specific indemnification provisions contained in the Delaware General Corporation Law. These indemnification agreements generally require us, among other things, to indemnify our officers and directors against certain liabilities that may arise by reason of their status or service as directors or officers, other than liabilities arising from willful misconduct. These indemnification agreements also generally require us to advance any expenses incurred by the directors or officers as a result of any proceeding against them as to which they could be indemnified. These indemnification provisions and the indemnification agreements may be sufficiently broad to permit indemnification of our officers and directors for liabilities, including reimbursement of expenses incurred, arising under the Securities Act.

The Registrant has purchased and currently intends to maintain insurance on behalf of each and every person who is or was a director or officer of the Registrant against any loss arising from any claim asserted against him or her and incurred by him or her in any such capacity, subject to certain exclusions.

The foregoing summaries are necessarily subject to the complete text of the referenced sections of the Delaware General Corporation Law, our Amended and Restated Certificate of Incorporation, Amended and Restated Bylaws, and the form indemnification agreements and are qualified in their entirety by reference thereto.

ITEM 16. EXHIBITS AND FINANCIAL STATEMENT SCHEDULES

a. Exhibits

Exhibit No.	Description
3.1	Second Amended and Restated Certificate of Incorporation.(8)
3.2	Certificate of Amendment to the Company's Second Amended and Restated Certificate of Incorporation filed with Delaware Secretary of State on April 21, 2023 (3)
3.3	Second Amended and Restated Bylaws.(3)
4.1	Specimen Common Stock Certificate.(1)
4.2	Description of Registered Securities (8)
5.1	Opinion of Ellenoff Grossman & Schole LLP. (12)
5.2	Opinion of Ellenoff Grossman & Schole LLP. (1)
10.1	2019 Equity Incentive Plan.(1)
10.2	2022 Equity Incentive Plan.(10)
10.3	2019 Equity Incentive Plan Form of Stock Option Grant Agreement.(1)
10.4	2022 Equity Incentive Plan Form of Incentive Stock Option Agreement (Employee).(1)
10.5	2022 Equity Incentive Plan Form of Nonstatutory Stock Option Agreement (Consultant).(1)
10.6	2022 Equity Incentive Plan Form of Nonstatutory Stock Option Agreement (Non-Employee Director).(1)
10.7	2022 Equity Incentive Plan Form of Nonstatutory Stock Option Agreement (Employee).(1)
10.8	Exclusive License Agreement between the Registrant and Children's Hospital Medical Center, d/b/a Cincinnati Children's Hospital Medical Center, effective as of June 1, 2021.(2)
10.9	License Agreement between the Registrant and Oxford University Innovation Limited, effective as of July 16, 2019.(2)
10.10	Exclusive License Agreement between the Registrant and St. Jude Children's Research Hospital, Inc., effective as of January 27, 2020.(2)
10.11	Lease Agreement, dated as of April 29, 2021, between the Registrant and Regus Management Group, LLC.(1)
10.12	Master Services Agreement between the Registrant and Ology Bioservices, Inc., effective as of July 19, 2019.(1)
10.13	Project Addendum 1 to Master Services Agreement between the Registrant and Ology Bioservices, Inc., effective as of October 9, 2019.(1)
10.14	Letter Agreement between the Registrant and Ology Bioservices, Inc., dated as of January 9, 2020.(1)
10.15	Project Addendum II to Master Services Agreement between the Registrant and Ology Bioservices, Inc., effective as of May 21, 2021.(1)
10.16	Form of Employment Agreement with Joseph Hernandez.(1)
10.17	Form of Employment Agreement with Erin Henderson.(1)
10.18	Form of Employment Agreement with Jon Garfield.(1)
10.19	Form of Indemnification Agreement for Directors and Officers.(1)
10.20	Form of Securities Purchase Agreement, dated as of April 13, 2022, by and among the Company and the Purchasers.(5)
10.21	Form of Registration Rights Agreement, dated as of April 13, 2022, by and among the Company and the Purchasers.(5)
10.22	Form of Securities Purchase Agreement, dated as of August 9, 2022, by and among the Company and the Purchasers.(6)
10.23	Form of Registration Rights Agreement, dated as of August 9, 2022, by and among the Company and the Purchasers.(6)
10.24	Settlement Agreement and Release, dated October 9, 2022, by and between the Registrant and Boustead Securities, LLC.(8)
10.25	Amendment No. 1 to Project Addendum 2 to Master Services Agreement, dated as of April 20, 2022, by and between the Registrant and Ology Bioservices, Inc.(9)
10.26	Amendment #1 to Exclusive License Agreement, dated as of May 11, 2022, by and between the Registrant and St. Jude Children's Research Hospital, Inc.(9)
10.27	Asset Purchase Agreement, dated as of April 19, 2023, between Veru, Inc. and the Registrant (11)
10.28	Form of Non-Competition and Non-Solicitation Agreement, dated as of April 19, 2023 (11)
10.29	Promissory Note, dated April 19, 2023*
10.30	Promissory Note, dated April 19, 2023*
10.31	Promissory Note, dated April 19, 2023*
14	Code of Ethics.(2)
23.1	Consent of Mayer Hoffman McCann P.C.*
23.2	Consent of Ellenoff Grossman & Schole LLP (included in exhibit 5.1)
23.3	Consent of Ellenoff Grossman & Schole LLP (included in exhibit 5.2)
24.1	Power of Attorney (included on signature page to this Registration Statement).*
107	Filing Fee Table*

* Filed herewith.

(1) Incorporated by reference to the Company's Registration Statement on Form S-1, filed with the SEC on August 29, 2022.

(2) Incorporated by reference to the Company's Registration Statement on Form S-1/A, filed with the SEC on November 5, 2021.

(3) Incorporated by reference to the Company's Current Report on Form 8-K, filed with the SEC on April 24, 2023.

(4) Incorporated by reference to the Company's Registration Statement on Form S-1/A, filed with the SEC on November 29, 2021.
(5) Incorporated by reference to the Company's Current Report on Form 8-K, filed with the SEC on April 19, 2022.
(6) Incorporated by reference to the Company's Current Report on Form 8-K, filed with the SEC on August 11, 2022.
(7) Incorporated by reference to the Company's Quarterly Report on Form 10-Q, filed with the SEC on November 1, 2022.
(8) Incorporated by reference to the Company's Annual Report on Form 10-K, filed with the SEC on March 31, 2022.
(9) Incorporated by reference to the Company's Quarterly Report on Form 10-Q, filed with the SEC on May 13, 2022.
(10) Incorporated by reference to the Company's Definitive Proxy Statement on Schedule 14A, filed with the SEC on July 18, 2022.
(11) Incorporated by reference to the Company's Current Report on Form 8-K, filed with the SEC on April 20, 2023.
(12) Incorporated by reference to the Company's Registration Statement on Form S-1/A, filed with the SEC on May 3, 2022.

b. Financial Statement Schedules

All financial statement schedules have been omitted since the required information is not applicable or is not present in amounts sufficient to require submission of the schedule, or because the information required is included in the financial statements and notes thereto.

ITEM 17. UNDERTAKINGS

The undersigned registrant hereby undertakes:

(1) To file, during any period in which offers or sales are being made, a post-effective amendment to this registration statement:

(i) To include any prospectus required by Section 10(a)(3) of the Securities Act of 1933;

(ii) To reflect in the prospectus any facts or events arising after the effective date of the registration statement (or the most recent post-effective amendment thereof) which, individually or in the aggregate, represent a fundamental change in the information set forth in the registration statement. Notwithstanding the foregoing, any increase or decrease in volume of securities offered (if the total dollar value of securities offered would not exceed that which was registered) and any deviation from the low or high end of the estimated maximum offering range may be reflected in the form of prospectus filed with the Securities and Exchange Commission pursuant to Rule 424(b) if, in the aggregate, the changes in volume and price represent no more than a 20% change in the maximum aggregate offering price set forth in the "Calculation of Registration Fee" table in the effective registration statement; and

(iii) To include any material information with respect to the plan of distribution not previously disclosed in the registration statement or any material change to such information in the registration statement;

(2) That, for the purpose of determining any liability under the Securities Act of 1933, each such post-effective amendment shall be deemed to be a new registration statement relating to the securities offered therein, and the offering of such securities at that time shall be deemed to be the initial bona fide offering thereof.

(3) To remove from registration by means of a post-effective amendment any of the securities being registered which remain unsold at the termination of the offering.

(4) That, for the purpose of determining liability under the Securities Act of 1933 to any purchaser, each prospectus filed pursuant to Rule 424(b) as part of a registration statement relating to an offering, other than registration statements relying on Rule 430B or other than prospectuses filed in reliance on Rule 430A (§230.430A of this chapter), shall be deemed to be part of and included in the registration statement as of the date it is first used after effectiveness. Provided, however, that no statement made in a registration statement or prospectus that is part of the registration statement or made in a document incorporated or deemed incorporated by reference into the registration statement or prospectus that is part of the registration statement will, as to a purchaser with a time of contract of sale prior to such first use, supersede or modify any statement that was made in the registration statement or prospectus that was part of the registration statement or made in any such document immediately prior to such date of first use.

(5) That, for the purpose of determining liability of the registrant under the Securities Act of 1933 to any purchaser in the initial distribution of the securities:

The undersigned registrant undertakes that in a primary offering of securities of the undersigned registrant pursuant to this registration statement, regardless of the underwriting method used to sell the securities to the purchaser, if the securities are offered or sold to such purchaser by means of any of the following communications, the undersigned registrant will be a seller to the purchaser and will be considered to offer or sell such securities to such purchaser:

(i) Any preliminary prospectus or prospectus of the undersigned registrant relating to the offering required to be filed pursuant to Rule 424;

(ii) Any free writing prospectus relating to the offering prepared by or on behalf of the undersigned registrant or used or referred to by the undersigned registrant;

(iii) The portion of any other free writing prospectus relating to the offering containing material information about the undersigned registrant or its securities provided by or on behalf of the undersigned registrant; and

(iv) Any other communication that is an offer in the offering made by the undersigned registrant to the purchaser.

Insofar as indemnification for liabilities arising under the Securities Act of 1933 may be permitted to directors, officers and controlling persons of the registrant pursuant to the foregoing provisions, or otherwise, the registrant has been advised that in the opinion of the Securities and Exchange Commission such indemnification is against public policy as expressed in the Securities Act of 1933 and is, therefore, unenforceable. In the event that a claim for indemnification against such liabilities (other than the payment by the registrant of expenses incurred or paid by a director, officer or controlling person of the registrant in the successful defense of any action, suit or proceeding) is asserted by such director, officer or controlling person in connection with the securities being registered, the registrant will, unless in the opinion of its counsel the matter has been settled by controlling precedent, submit to a court of appropriate jurisdiction the question whether such indemnification by it is against public policy as expressed in the Securities Act of 1933 and will be governed by the final adjudication of such issue.

SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

KNOW ALL PERSONS BY THESE PRESENTS that each individual whose signature appears below hereby constitutes and appoints Joseph Hernandez and Jon Garfield and each of them, as his or her true and lawful attorney-in- fact and agent with full power of substitution, for him or her and in his or her name, place and stead, in any and all capacities, to sign any and all amendments, including post-effective amendments, to this registration statement, and to sign any registration statement for the same offering covered by this registration statement that is to be effective upon filing pursuant to Rule 462(b) promulgated under the Securities Act of 1933 increasing the number of shares for which registration is sought, and all post-effective amendments thereto, and to file the same, with all exhibits thereto and all documents in connection therewith, making such changes in this registration statement as such attorney-in-fact and agent so acting deem appropriate, with the SEC, granting unto said attorney-in-fact and agent, and each of them, full power and authority to do and perform each and every act and thing requisite and necessary to be done with respect to the offering of securities contemplated by this registration statement, as fully to all intents and purposes as he or she might or could do in person, hereby ratifying and confirming all that said attorneys-in-fact and agent or any of them, or his, her or their substitute or substitutes, may lawfully do or cause to be done or by virtue hereof.

Blue Water Biotech, Inc.

Date: April 28, 2023

By: */s/ Joseph Hernandez*
Joseph Hernandez
Chairman of the Board and Chief Executive Officer
(principal executive officer)

Pursuant to the requirements of the Securities Exchange Act of 1934, this report has been signed below by the following persons on behalf of the registrant and in the capacities indicated on April 28, 2023.

Signature	Title
/s/ Joseph Hernandez Joseph Hernandez	Chairman of the Board and Chief Executive Officer (principal executive officer)
/s/ Jon Garfield Jon Garfield	Chief Financial Officer (principal financial and accounting officer)
/s/ Vuk Jemerić Vuk Jemerić	Director
/s/ Timothy Ramdeen Timothy Ramdeen	Director
/s/ James Sapirstein James Sapirstein	Director
/s/ Simon Tarsh Simon Tarsh	Director

Exhibit 10.29

THE SECURITY REPRESENTED HEREBY HAS NOT BEEN REGISTERED UNDER THE SECURITIES ACT OF 1933, AS AMENDED, OR ANY APPLICABLE STATE SECURITIES LAWS (THE "SECURITIES ACTS"), AND IS NOT TRANSFERABLE, EXCEPT IN ACCORDANCE WITH THE SECURITIES ACTS OR AS SET FORTH HEREIN.

$4,000,000 April 19, 2023

PROMISSORY NOTE

FOR VALUE RECEIVED, the undersigned, BLUE WATER VACCINES, INC., a Delaware corporation ("Borrower"), promises to pay to the order of VERU INC., a Wisconsin corporation (together with its successors and assigns, "Holder"), at such address as Holder may designate to Borrower in writing, the principal sum of Four Million and 00/100 Dollars ($4,000,000), due and payable as set forth herein. This Note shall not bear interest except as provided in Section 5.

1. Asset Purchase Agreement. This Promissory Note (this "Note") has been executed and delivered pursuant to and in accordance with the terms and conditions of that certain Asset Purchase Agreement dated as of the date hereof between Borrower and Holder (the "Purchase Agreement"). This Note is subject to the terms and conditions of the Purchase Agreement, which are, by this reference, incorporated herein and made a part hereof, including the right of setoff described below. Capitalized terms used in this Note without definition shall have the meanings set forth in the Purchase Agreement.

2. Payment of Principal. The unpaid principal balance of this Note shall be payable by Borrower to Holder on September 30, 2023 (the "Maturity Date"). On the Maturity Date, all unpaid principal shall be due and payable in full. All payments of principal on this Note shall be made in lawful United States currency by wire transfer of immediately available funds to an account as Holder shall designate to Borrower in writing (or, if Holder has not designated an account for wire transfer, by certified check sent to Holder's address in accordance with Section 11.03 of the Purchase Agreement). If any payment of principal pursuant to this Note is due on a day which is not a Business Day, such payment shall be due on the next succeeding Business Day.

3. Prepayments.

(a) Voluntary Prepayments. Voluntary prepayments in whole or in part may be made by Borrower under this Note at any time without penalty.

(b) Mandatory Prepayment. Upon the occurrence of a Change of Control (as defined below), Borrower shall prepay all of the outstanding principal under this Note on the effective date of such Change of Control. For purpose of this Note, a "Change of Control" means a transaction or series of transactions pursuant to which any Person or affiliated group of Persons, other than the stockholders of Borrower as of the date hereof or any of their respective Affiliates, acquires (i) equity securities of Borrower possessing 51.0% or more of the ordinary voting power of Borrower (whether by merger, consolidation or sale or transfer of equity securities) or (ii) all or substantially all of the assets of Borrower.

4. Event of Default. The occurrence of any one or more of the following events with respect to Borrower shall constitute an event of default hereunder (an "Event of Default"):

(a) Borrower fails to pay all or any portion of any amount due hereunder when the same becomes due and payable, whether at a stated payment date or by acceleration and such failure to timely pay continues uncured for a period of five (5) days after the date such amount becomes due;

(b) Borrower becomes insolvent or fails generally to pay its material debts as they become due;

(c) the taking of action by Borrower to become the subject of proceedings under the United States Bankruptcy Code; or the execution by Borrower of a petition to become a debtor under the United States Bankruptcy Code; or the entry of an order for relief under the United States Bankruptcy Code against Borrower; or Borrower making an assignment for the benefit of creditors; or Borrower consenting to the appointment of a custodian, receiver, trustee or other officer with similar powers with respect to Borrower, or with respect to any substantial part of its property; or adjudicating of Borrower as insolvent; or

(d) if any governmental authority of competent jurisdiction shall enter an order appointing, without the consent of Borrower, a custodian, receiver, trustee or other officer with similar powers with respect to Borrower, or with respect to any substantial part of its property; or if an order for relief relating to Borrower shall be entered in any case or proceeding for liquidation or reorganization or otherwise to take advantage of any bankruptcy or insolvency law of any jurisdiction, or ordering the dissolution, winding-up or liquidation of Borrower; or if any petition for any such relief shall be filed against Borrower and such petition shall not be dismissed or stayed within sixty (60) days.

5. Accrual of Interest. After the Maturity Date, or the earlier acceleration of the indebtedness evidenced by this Note, or if said indebtedness has not been accelerated, during any period in which an Event of Default occurs and continues under this Note, Holder may elect to accrue interest on the unpaid principal amount of this Note outstanding during any such period at the rate of ten percent (10%) per annum (the "Default Interest Rate"). In no contingency or event whatsoever shall the interest rate charged hereunder exceed the highest rate permissible under any law which a court of competent jurisdiction shall, in a final determination, deem applicable hereto. In the event that such a court determines that Holder has received interest hereunder in excess of the highest rate applicable hereto, Holder shall promptly refund such excess interest to Borrower.

6. Remedies Cumulative. Upon the occurrence and during the continuance of an Event of Default, at Holder's option, upon notice by Holder to or demand by Holder of Borrower: (a) all amounts due and owing from Borrower to Holder under this Note shall be due and payable forthwith; and (b) Holder, at its option, may enforce or cause to be enforced any of the rights or remedies accorded to Holder in this Note, or at law or in equity, by virtue of statute or otherwise. The rights and remedies of Holder under this Note shall be cumulative and not alternative. No waiver by Holder of any right or remedy under this Note or any Event of Default shall be effective unless in a writing signed by Holder. Neither the failure nor any delay in exercising any right, power or privilege under this Note will operate as a waiver of such right, power or privilege and no single or partial exercise of any such right, power or privilege by Holder will preclude any other or further exercise of such right, power or privilege or the exercise of any other right, power or privilege. Borrower waives presentment, demand, notice, protest and all other demands and notices in connection with the delivery, acceptance, performance, default or enforcement of this Note. If any suit or action is instituted or attorneys are employed to collect or enforce this Note or any part thereof, Borrower promises and agrees to pay all reasonable and documented costs of collection and enforcement, including reasonable and documented attorneys' fees and court costs.

7. Setoff. Borrower shall be entitled to set off amounts due Holder pursuant to this Note in accordance with Section 10.02(g) of the Purchase Agreement. Any amounts setoff shall be applied against any outstanding principal. Borrower may only exercise its right of setoff pursuant to this Section 7: (a) with respect to a claim or a Third Party Claim for which Holder has received written notice in accordance with the provisions of Sections 10.04 and 11.03 of the Purchase Agreement and (b) if such setoff relates to a Third Party Claim for which Holder has assumed the defense pursuant to Section 10.04(b) of the Purchase Agreement, as to Buyer's Damages constituting actual amounts paid by a Buyer Indemnified Party pursuant to a settlement or a final judgment (not subject to further appeal) of such Third Party Claim made in accordance with Section 10.04(b) of the Purchase Agreement. The exercise of such right of setoff by Borrower in compliance with Section 10.02(g) of the Purchase Agreement and this Section 7 will not constitute an Event of Default or breach of this Note and shall not trigger interest at the Default Interest Rate; provided, however, that if (i) such setoff is determined not to have been in compliance with Section 10.02(g) of the Purchase Agreement and this Section 7, (ii) Borrower ultimately fails to prevail with respect to the underlying claim relating to such setoff, or (iii) such setoff is determined not to have been a good faith estimate of the amount of liability in connection with such claim, then Borrower's exercise of such right of setoff shall trigger interest at the Default Interest Rate. Borrower's only setoff rights with respect to amounts due Holder pursuant to this Note are as expressly set forth in Section 10.02(g) of the Purchase Agreement and this Section 7.

8. Governing Law; Submission to Jurisdiction; Waiver of Jury Trial.

(a) This Note shall be governed by the Laws of the State of Delaware without giving effect to any rule or provision thereof which would cause the application of the Law of any other state.

(b) ANY LEGAL SUIT, ACTION OR PROCEEDING ARISING OUT OF OR BASED UPON THIS NOTE MAY ONLY BE INSTITUTED IN THE FEDERAL COURTS OF THE UNITED STATES OF AMERICA OR THE COURTS OF THE STATE OF DELAWARE, AND EACH PARTY IRREVOCABLY SUBMITS TO THE EXCLUSIVE JURISDICTION OF SUCH COURTS IN ANY SUCH SUIT, ACTION OR PROCEEDING. SERVICE OF PROCESS, SUMMONS, NOTICE OR OTHER DOCUMENT DELIVERED TO A PARTY IN ACCORDANCE WITH SECTION 9 HEREOF SHALL BE EFFECTIVE SERVICE OF PROCESS FOR ANY SUIT, ACTION OR OTHER PROCEEDING BROUGHT IN ANY SUCH COURT. THE PARTIES IRREVOCABLY AND UNCONDITIONALLY WAIVE ANY OBJECTION TO THE LAYING OF VENUE OF ANY SUIT, ACTION OR ANY PROCEEDING IN SUCH COURTS AND IRREVOCABLY WAIVE AND AGREE NOT TO PLEAD OR CLAIM IN ANY SUCH COURT THAT ANY SUCH SUIT, ACTION OR PROCEEDING BROUGHT IN ANY SUCH COURT HAS BEEN BROUGHT IN AN INCONVENIENT FORUM.

(c) EACH PARTY ACKNOWLEDGES AND AGREES THAT ANY CONTROVERSY WHICH MAY ARISE UNDER THIS NOTE IS LIKELY TO INVOLVE COMPLICATED AND DIFFICULT ISSUES AND, THEREFORE, EACH SUCH PARTY IRREVOCABLY AND UNCONDITIONALLY WAIVES ANY RIGHT IT MAY HAVE TO A TRIAL BY JURY IN RESPECT OF ANY LEGAL ACTION ARISING OUT OF OR RELATING TO THIS NOTE. EACH PARTY CERTIFIES AND ACKNOWLEDGES THAT (I) NO REPRESENTATIVE OF ANY OTHER PARTY HAS REPRESENTED, EXPRESSLY OR OTHERWISE, THAT SUCH OTHER PARTY WOULD NOT SEEK TO ENFORCE THE FOREGOING WAIVER IN THE EVENT OF A LEGAL ACTION, (II) SUCH PARTY HAS CONSIDERED THE IMPLICATIONS OF THIS WAIVER, (III) SUCH PARTY MAKES THIS WAIVER VOLUNTARILY, AND (IV) SUCH PARTY HAS BEEN INDUCED TO ENTER INTO OR ACCEPT THIS NOTE, AS APPLICABLE, BY, AMONG OTHER THINGS, THE MUTUAL WAIVERS AND CERTIFICATIONS IN THIS SECTION 8(C).

9. Notices. All notices under this Note shall be given in accordance with Section 11.03 of the Purchase Agreement.

10. Time is of the Essence. Time is of the essence in Borrower's performance of its obligations under this Note.

11. Miscellaneous. This Note shall bind Borrower and its successors and permitted assigns and shall inure to the benefit of Holder and its successors, permitted assigns, heirs and representatives. Neither party may assign this Note or delegate its duties hereunder without the other party's prior written consent, and any such purported assignment or delegation of duties shall be null and void. This Note may not be changed orally, but only by an agreement in writing signed by Holder and Borrower. After all amounts at any time owed on this Note have been paid in full, this Note will be surrendered to Borrower for cancellation and will not be reissued.

[Signature page follows.]

IN WITNESS WHEREOF, the undersigned has executed this Promissory Note as of the date first written above.

BORROWER:

BLUE WATER VACCINES, INC.

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

[Signature Page to Asset Purchase Agreement Note]

Exhibit 10.30

THE SECURITY REPRESENTED HEREBY HAS NOT BEEN REGISTERED UNDER THE SECURITIES ACT OF 1933, AS AMENDED, OR ANY APPLICABLE STATE SECURITIES LAWS (THE "SECURITIES ACTS"), AND IS NOT TRANSFERABLE, EXCEPT IN ACCORDANCE WITH THE SECURITIES ACTS OR AS SET FORTH HEREIN.

$5,000,000 April 19, 2023

PROMISSORY NOTE

FOR VALUE RECEIVED, the undersigned, BLUE WATER VACCINES, INC., a Delaware corporation ("Borrower"), promises to pay to the order of VERU INC., a Wisconsin corporation (together with its successors and assigns, "Holder"), at such address as Holder may designate to Borrower in writing, the principal sum of Five Million and 00/100 Dollars ($5,000,000), due and payable as set forth herein. This Note shall not bear interest except as provided in Section 5.

1. Asset Purchase Agreement. This Promissory Note (this "Note") has been executed and delivered pursuant to and in accordance with the terms and conditions of that certain Asset Purchase Agreement dated as of the date hereof between Borrower and Holder (the "Purchase Agreement"). This Note is subject to the terms and conditions of the Purchase Agreement, which are, by this reference, incorporated herein and made a part hereof, including the right of setoff described below. Capitalized terms used in this Note without definition shall have the meanings set forth in the Purchase Agreement.

2. Payment of Principal. The unpaid principal balance of this Note shall be payable by Borrower to Holder on April 19, 2024 (the "Maturity Date"). On the Maturity Date, all unpaid principal shall be due and payable in full. All payments of principal on this Note shall be made in lawful United States currency by wire transfer of immediately available funds to an account as Holder shall designate to Borrower in writing (or, if Holder has not designated an account for wire transfer, by certified check sent to Holder's address in accordance with Section 11.03 of the Purchase Agreement). If any payment of principal pursuant to this Note is due on a day which is not a Business Day, such payment shall be due on the next succeeding Business Day.

3. Prepayments.

(a) Voluntary Prepayments. Voluntary prepayments in whole or in part may be made by Borrower under this Note at any time without penalty.

(b) Mandatory Prepayment. Upon the occurrence of a Change of Control (as defined below), Borrower shall prepay all of the outstanding principal under this Note on the effective date of such Change of Control. For purpose of this Note, a "Change of Control" means a transaction or series of transactions pursuant to which any Person or affiliated group of Persons, other than the stockholders of Borrower as of the date hereof or any of their respective Affiliates, acquires (i) equity securities of Borrower possessing 51.0% or more of the ordinary voting power of Borrower (whether by merger, consolidation or sale or transfer of equity securities) or (ii) all or substantially all of the assets of Borrower.

4. Event of Default. The occurrence of any one or more of the following events with respect to Borrower shall constitute an event of default hereunder (an "Event of Default"):

(a) Borrower fails to pay all or any portion of any amount due hereunder when the same becomes due and payable, whether at a stated payment date or by acceleration and such failure to timely pay continues uncured for a period of five (5) days after the date such amount becomes due;

(b) Borrower becomes insolvent or fails generally to pay its material debts as they become due;

(c) the taking of action by Borrower to become the subject of proceedings under the United States Bankruptcy Code; or the execution by Borrower of a petition to become a debtor under the United States Bankruptcy Code; or the entry of an order for relief under the United States Bankruptcy Code against Borrower; or Borrower making an assignment for the benefit of creditors; or Borrower consenting to the appointment of a custodian, receiver, trustee or other officer with similar powers with respect to Borrower, or with respect to any substantial part of its property; or adjudicating of Borrower as insolvent; or

(d) if any governmental authority of competent jurisdiction shall enter an order appointing, without the consent of Borrower, a custodian, receiver, trustee or other officer with similar powers with respect to Borrower, or with respect to any substantial part of its property; or if an order for relief relating to Borrower shall be entered in any case or proceeding for liquidation or reorganization or otherwise to take advantage of any bankruptcy or insolvency law of any jurisdiction, or ordering the dissolution, winding-up or liquidation of Borrower; or if any petition for any such relief shall be filed against Borrower and such petition shall not be dismissed or stayed within sixty (60) days.

5. Accrual of Interest. After the Maturity Date, or the earlier acceleration of the indebtedness evidenced by this Note, or if said indebtedness has not been accelerated, during any period in which an Event of Default occurs and continues under this Note, Holder may elect to accrue interest on the unpaid principal amount of this Note outstanding during any such period at the rate of ten percent (10%) per annum (the "Default Interest Rate"). In no contingency or event whatsoever shall the interest rate charged hereunder exceed the highest rate permissible under any law which a court of competent jurisdiction shall, in a final determination, deem applicable hereto. In the event that such a court determines that Holder has received interest hereunder in excess of the highest rate applicable hereto, Holder shall promptly refund such excess interest to Borrower.

6. Remedies Cumulative. Upon the occurrence and during the continuance of an Event of Default, at Holder's option, upon notice by Holder to or demand by Holder of Borrower: (a) all amounts due and owing from Borrower to Holder under this Note shall be due and payable forthwith; and (b) Holder, at its option, may enforce or cause to be enforced any of the rights or remedies accorded to Holder in this Note, or at law or in equity, by virtue of statute or otherwise. The rights and remedies of Holder under this Note shall be cumulative and not alternative. No waiver by Holder of any right or remedy under this Note or any Event of Default shall be effective unless in a writing signed by Holder. Neither the failure nor any delay in exercising any right, power or privilege under this Note will operate as a waiver of such right, power or privilege and no single or partial exercise of any such right, power or privilege by Holder will preclude any other or further exercise of such right, power or privilege or the exercise of any other right, power or privilege. Borrower waives presentment, demand, notice, protest and all other demands and notices in connection with the delivery, acceptance, performance, default or enforcement of this Note. If any suit or action is instituted or attorneys are employed to collect or enforce this Note or any part thereof, Borrower promises and agrees to pay all reasonable and documented costs of collection and enforcement, including reasonable and documented attorneys' fees and court costs.

7. Setoff. Borrower shall be entitled to set off amounts due Holder pursuant to this Note in accordance with Section 10.02(g) of the Purchase Agreement. Any amounts setoff shall be applied against any outstanding principal. Borrower may only exercise its right of setoff pursuant to this Section 7: (a) with respect to a claim or a Third Party Claim for which Holder has received written notice in accordance with the provisions of Sections 10.04 and 11.03 of the Purchase Agreement and (b) if such setoff relates to a Third Party Claim for which Holder has assumed the defense pursuant to Section 10.04(b) of the Purchase Agreement, as to Buyer's Damages constituting actual amounts paid by a Buyer Indemnified Party pursuant to a settlement or a final judgment (not subject to further appeal) of such Third Party Claim made in accordance with Section 10.04(b) of the Purchase Agreement. The exercise of such right of setoff by Borrower in compliance with Section 10.02(g) of the Purchase Agreement and this Section 7 will not constitute an Event of Default or breach of this Note and shall not trigger interest at the Default Interest Rate; provided, however, that if (i) such setoff is determined not to have been in compliance with Section 10.02(g) of the Purchase Agreement and this Section 7, (ii) Borrower ultimately fails to prevail with respect to the underlying claim relating to such setoff, or (iii) such setoff is determined not to have been a good faith estimate of the amount of liability in connection with such claim, then Borrower's exercise of such right of setoff shall trigger interest at the Default Interest Rate. Borrower's only setoff rights with respect to amounts due Holder pursuant to this Note are as expressly set forth in Section 10.02(g) of the Purchase Agreement and this Section 7.

8. Governing Law; Submission to Jurisdiction; Waiver of Jury Trial.

(a) This Note shall be governed by the Laws of the State of Delaware without giving effect to any rule or provision thereof which would cause the application of the Law of any other state.

(b) ANY LEGAL SUIT, ACTION OR PROCEEDING ARISING OUT OF OR BASED UPON THIS NOTE MAY ONLY BE INSTITUTED IN THE FEDERAL COURTS OF THE UNITED STATES OF AMERICA OR THE COURTS OF THE STATE OF DELAWARE, AND EACH PARTY IRREVOCABLY SUBMITS TO THE EXCLUSIVE JURISDICTION OF SUCH COURTS IN ANY SUCH SUIT, ACTION OR PROCEEDING. SERVICE OF PROCESS, SUMMONS, NOTICE OR OTHER DOCUMENT DELIVERED TO A PARTY IN ACCORDANCE WITH SECTION 9 HEREOF SHALL BE EFFECTIVE SERVICE OF PROCESS FOR ANY SUIT, ACTION OR OTHER PROCEEDING BROUGHT IN ANY SUCH COURT. THE PARTIES IRREVOCABLY AND UNCONDITIONALLY WAIVE ANY OBJECTION TO THE LAYING OF VENUE OF ANY SUIT, ACTION OR ANY PROCEEDING IN SUCH COURTS AND IRREVOCABLY WAIVE AND AGREE NOT TO PLEAD OR CLAIM IN ANY SUCH COURT THAT ANY SUCH SUIT, ACTION OR PROCEEDING BROUGHT IN ANY SUCH COURT HAS BEEN BROUGHT IN AN INCONVENIENT FORUM.

(c) EACH PARTY ACKNOWLEDGES AND AGREES THAT ANY CONTROVERSY WHICH MAY ARISE UNDER THIS NOTE IS LIKELY TO INVOLVE COMPLICATED AND DIFFICULT ISSUES AND, THEREFORE, EACH SUCH PARTY IRREVOCABLY AND UNCONDITIONALLY WAIVES ANY RIGHT IT MAY HAVE TO A TRIAL BY JURY IN RESPECT OF ANY LEGAL ACTION ARISING OUT OF OR RELATING TO THIS NOTE. EACH PARTY CERTIFIES AND ACKNOWLEDGES THAT (I) NO REPRESENTATIVE OF ANY OTHER PARTY HAS REPRESENTED, EXPRESSLY OR OTHERWISE, THAT SUCH OTHER PARTY WOULD NOT SEEK TO ENFORCE THE FOREGOING WAIVER IN THE EVENT OF A LEGAL ACTION, (II) SUCH PARTY HAS CONSIDERED THE IMPLICATIONS OF THIS WAIVER, (III) SUCH PARTY MAKES THIS WAIVER VOLUNTARILY, AND (IV) SUCH PARTY HAS BEEN INDUCED TO ENTER INTO OR ACCEPT THIS NOTE, AS APPLICABLE, BY, AMONG OTHER THINGS, THE MUTUAL WAIVERS AND CERTIFICATIONS IN THIS SECTION 8(C).

9. Notices. All notices under this Note shall be given in accordance with Section 11.03 of the Purchase Agreement.

10. Time is of the Essence. Time is of the essence in Borrower's performance of its obligations under this Note.

11. Miscellaneous. This Note shall bind Borrower and its successors and permitted assigns and shall inure to the benefit of Holder and its successors, permitted assigns, heirs and representatives. Neither party may assign this Note or delegate its duties hereunder without the other party's prior written consent, and any such purported assignment or delegation of duties shall be null and void. This Note may not be changed orally, but only by an agreement in writing signed by Holder and Borrower. After all amounts at any time owed on this Note have been paid in full, this Note will be surrendered to Borrower for cancellation and will not be reissued.

[Signature page follows.]

IN WITNESS WHEREOF, the undersigned has executed this Promissory Note as of the date first written above.

BORROWER:

BLUE WATER VACCINES, INC.

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

[Signature Page to Asset Purchase Agreement Note]

Exhibit 10.31

THE SECURITY REPRESENTED HEREBY HAS NOT BEEN REGISTERED UNDER THE SECURITIES ACT OF 1933, AS AMENDED, OR ANY APPLICABLE STATE SECURITIES LAWS (THE "SECURITIES ACTS"), AND IS NOT TRANSFERABLE, EXCEPT IN ACCORDANCE WITH THE SECURITIES ACTS OR AS SET FORTH HEREIN.

$5,000,000 April 19, 2023

PROMISSORY NOTE

FOR VALUE RECEIVED, the undersigned, BLUE WATER VACCINES, INC., a Delaware corporation ("Borrower"), promises to pay to the order of VERU INC., a Wisconsin corporation (together with its successors and assigns, "Holder"), at such address as Holder may designate to Borrower in writing, the principal sum of Five Million and 00/100 Dollars ($5,000,000), due and payable as set forth herein. This Note shall not bear interest except as provided in Section 5.

1. Asset Purchase Agreement. This Promissory Note (this "Note") has been executed and delivered pursuant to and in accordance with the terms and conditions of that certain Asset Purchase Agreement dated as of the date hereof between Borrower and Holder (the "Purchase Agreement"). This Note is subject to the terms and conditions of the Purchase Agreement, which are, by this reference, incorporated herein and made a part hereof, including the right of setoff described below. Capitalized terms used in this Note without definition shall have the meanings set forth in the Purchase Agreement.

2. Payment of Principal. The unpaid principal balance of this Note shall be payable by Borrower to Holder on September 30, 2024 (the "Maturity Date"). On the Maturity Date, all unpaid principal shall be due and payable in full. All payments of principal on this Note shall be made in lawful United States currency by wire transfer of immediately available funds to an account as Holder shall designate to Borrower in writing (or, if Holder has not designated an account for wire transfer, by certified check sent to Holder's address in accordance with Section 11.03 of the Purchase Agreement). If any payment of principal pursuant to this Note is due on a day which is not a Business Day, such payment shall be due on the next succeeding Business Day.

3. Prepayments.

(a) Voluntary Prepayments. Voluntary prepayments in whole or in part may be made by Borrower under this Note at any time without penalty.

(b) Mandatory Prepayment. Upon the occurrence of a Change of Control (as defined below), Borrower shall prepay all of the outstanding principal under this Note on the effective date of such Change of Control. For purpose of this Note, a "Change of Control" means a transaction or series of transactions pursuant to which any Person or affiliated group of Persons, other than the stockholders of Borrower as of the date hereof or any of their respective Affiliates, acquires (i) equity securities of Borrower possessing 51.0% or more of the ordinary voting power of Borrower (whether by merger, consolidation or sale or transfer of equity securities) or (ii) all or substantially all of the assets of Borrower.

4. Event of Default. The occurrence of any one or more of the following events with respect to Borrower shall constitute an event of default hereunder (an "Event of Default"):

(a) Borrower fails to pay all or any portion of any amount due hereunder when the same becomes due and payable, whether at a stated payment date or by acceleration and such failure to timely pay continues uncured for a period of five (5) days after the date such amount becomes due;

(b) Borrower becomes insolvent or fails generally to pay its material debts as they become due;

(c) the taking of action by Borrower to become the subject of proceedings under the United States Bankruptcy Code; or the execution by Borrower of a petition to become a debtor under the United States Bankruptcy Code; or the entry of an order for relief under the United States Bankruptcy Code against Borrower; or Borrower making an assignment for the benefit of creditors; or Borrower consenting to the appointment of a custodian, receiver, trustee or other officer with similar powers with respect to Borrower, or with respect to any substantial part of its property; or adjudicating of Borrower as insolvent; or

(d) if any governmental authority of competent jurisdiction shall enter an order appointing, without the consent of Borrower, a custodian, receiver, trustee or other officer with similar powers with respect to Borrower, or with respect to any substantial part of its property; or if an order for relief relating to Borrower shall be entered in any case or proceeding for liquidation or reorganization or otherwise to take advantage of any bankruptcy or insolvency law of any jurisdiction, or ordering the dissolution, winding-up or liquidation of Borrower; or if any petition for any such relief shall be filed against Borrower and such petition shall not be dismissed or stayed within sixty (60) days.

5. Accrual of Interest. After the Maturity Date, or the earlier acceleration of the indebtedness evidenced by this Note, or if said indebtedness has not been accelerated, during any period in which an Event of Default occurs and continues under this Note, Holder may elect to accrue interest on the unpaid principal amount of this Note outstanding during any such period at the rate of ten percent (10%) per annum (the "Default Interest Rate"). In no contingency or event whatsoever shall the interest rate charged hereunder exceed the highest rate permissible under any law which a court of competent jurisdiction shall, in a final determination, deem applicable hereto. In the event that such a court determines that Holder has received interest hereunder in excess of the highest rate applicable hereto, Holder shall promptly refund such excess interest to Borrower.

6. Remedies Cumulative. Upon the occurrence and during the continuance of an Event of Default, at Holder's option, upon notice by Holder to or demand by Holder of Borrower: (a) all amounts due and owing from Borrower to Holder under this Note shall be due and payable forthwith; and (b) Holder, at its option, may enforce or cause to be enforced any of the rights or remedies accorded to Holder in this Note, or at law or in equity, by virtue of statute or otherwise. The rights and remedies of Holder under this Note shall be cumulative and not alternative. No waiver by Holder of any right or remedy under this Note or any Event of Default shall be effective unless in a writing signed by Holder. Neither the failure nor any delay in exercising any right, power or privilege under this Note will operate as a waiver of such right, power or privilege and no single or partial exercise of any such right, power or privilege by Holder will preclude any other or further exercise of such right, power or privilege or the exercise of any other right, power or privilege. Borrower waives presentment, demand, notice, protest and all other demands and notices in connection with the delivery, acceptance, performance, default or enforcement of this Note. If any suit or action is instituted or attorneys are employed to collect or enforce this Note or any part thereof, Borrower promises and agrees to pay all reasonable and documented costs of collection and enforcement, including reasonable and documented attorneys' fees and court costs.

7. Setoff. Borrower shall be entitled to set off amounts due Holder pursuant to this Note in accordance with Section 10.02(g) of the Purchase Agreement. Any amounts setoff shall be applied against any outstanding principal. Borrower may only exercise its right of setoff pursuant to this Section 7: (a) with respect to a claim or a Third Party Claim for which Holder has received written notice in accordance with the provisions of Sections 10.04 and 11.03 of the Purchase Agreement and (b) if such setoff relates to a Third Party Claim for which Holder has assumed the defense pursuant to Section 10.04(b) of the Purchase Agreement, as to Buyer's Damages constituting actual amounts paid by a Buyer Indemnified Party pursuant to a settlement or a final judgment (not subject to further appeal) of such Third Party Claim made in accordance with Section 10.04(b) of the Purchase Agreement. The exercise of such right of setoff by Borrower in compliance with Section 10.02(g) of the Purchase Agreement and this Section 7 will not constitute an Event of Default or breach of this Note and shall not trigger interest at the Default Interest Rate; provided, however, that if (i) such setoff is determined not to have been in compliance with Section 10.02(g) of the Purchase Agreement and this Section 7, (ii) Borrower ultimately fails to prevail with respect to the underlying claim relating to such setoff, or (iii) such setoff is determined not to have been a good faith estimate of the amount of liability in connection with such claim, then Borrower's exercise of such right of setoff shall trigger interest at the Default Interest Rate. Borrower's only setoff rights with respect to amounts due Holder pursuant to this Note are as expressly set forth in Section 10.02(g) of the Purchase Agreement and this Section 7.

8. Governing Law; Submission to Jurisdiction; Waiver of Jury Trial.

(a) This Note shall be governed by the Laws of the State of Delaware without giving effect to any rule or provision thereof which would cause the application of the Law of any other state.

(b) ANY LEGAL SUIT, ACTION OR PROCEEDING ARISING OUT OF OR BASED UPON THIS NOTE MAY ONLY BE INSTITUTED IN THE FEDERAL COURTS OF THE UNITED STATES OF AMERICA OR THE COURTS OF THE STATE OF DELAWARE, AND EACH PARTY IRREVOCABLY SUBMITS TO THE EXCLUSIVE JURISDICTION OF SUCH COURTS IN ANY SUCH SUIT, ACTION OR PROCEEDING. SERVICE OF PROCESS, SUMMONS, NOTICE OR OTHER DOCUMENT DELIVERED TO A PARTY IN ACCORDANCE WITH SECTION 9 HEREOF SHALL BE EFFECTIVE SERVICE OF PROCESS FOR ANY SUIT, ACTION OR OTHER PROCEEDING BROUGHT IN ANY SUCH COURT. THE PARTIES IRREVOCABLY AND UNCONDITIONALLY WAIVE ANY OBJECTION TO THE LAYING OF VENUE OF ANY SUIT, ACTION OR ANY PROCEEDING IN SUCH COURTS AND IRREVOCABLY WAIVE AND AGREE NOT TO PLEAD OR CLAIM IN ANY SUCH COURT THAT ANY SUCH SUIT, ACTION OR PROCEEDING BROUGHT IN ANY SUCH COURT HAS BEEN BROUGHT IN AN INCONVENIENT FORUM.

(c) EACH PARTY ACKNOWLEDGES AND AGREES THAT ANY CONTROVERSY WHICH MAY ARISE UNDER THIS NOTE IS LIKELY TO INVOLVE COMPLICATED AND DIFFICULT ISSUES AND, THEREFORE, EACH SUCH PARTY IRREVOCABLY AND UNCONDITIONALLY WAIVES ANY RIGHT IT MAY HAVE TO A TRIAL BY JURY IN RESPECT OF ANY LEGAL ACTION ARISING OUT OF OR RELATING TO THIS NOTE. EACH PARTY CERTIFIES AND ACKNOWLEDGES THAT (I) NO REPRESENTATIVE OF ANY OTHER PARTY HAS REPRESENTED, EXPRESSLY OR OTHERWISE, THAT SUCH OTHER PARTY WOULD NOT SEEK TO ENFORCE THE FOREGOING WAIVER IN THE EVENT OF A LEGAL ACTION, (II) SUCH PARTY HAS CONSIDERED THE IMPLICATIONS OF THIS WAIVER, (III) SUCH PARTY MAKES THIS WAIVER VOLUNTARILY, AND (IV) SUCH PARTY HAS BEEN INDUCED TO ENTER INTO OR ACCEPT THIS NOTE, AS APPLICABLE, BY, AMONG OTHER THINGS, THE MUTUAL WAIVERS AND CERTIFICATIONS IN THIS SECTION 8(C).

9. Notices. All notices under this Note shall be given in accordance with Section 11.03 of the Purchase Agreement.

10. Time is of the Essence. Time is of the essence in Borrower's performance of its obligations under this Note.

11. Miscellaneous. This Note shall bind Borrower and its successors and permitted assigns and shall inure to the benefit of Holder and its successors, permitted assigns, heirs and representatives. Neither party may assign this Note or delegate its duties hereunder without the other party's prior written consent, and any such purported assignment or delegation of duties shall be null and void. This Note may not be changed orally, but only by an agreement in writing signed by Holder and Borrower. After all amounts at any time owed on this Note have been paid in full, this Note will be surrendered to Borrower for cancellation and will not be reissued.

[Signature page follows.]

IN WITNESS WHEREOF, the undersigned has executed this Promissory Note as of the date first written above.

BORROWER:

BLUE WATER VACCINES, INC.

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

[Signature Page to Asset Purchase Agreement Note]

Exhibit 23.1

CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

We consent to the incorporation by reference in these Registration Statements on the Post-Effective Amendment No. 1 on Form S-3 to Form S-1 (File Nos. 333-267142 and 333-264646) and related prospectus of our report dated March 8, 2023, with respect to the financial statements of Blue Water Biotech, Inc., formerly known as Blue Water Vaccines Inc., (the "Company") as of December 31, 2022 and 2021, and for the two years then ended, included in the Company's Annual Report on Form 10-K for the year ended December 31, 2022, and to the reference to us under the heading "Experts" in the prospectus which is part of this Registration Statement.

/s/ Mayer Hoffman McCann P.C.

Los Angeles, California
April 28, 2023

Exhibit 107

Calculation of Filing Fee Tables

Form S-3
(Form Type)

Blue Water Biotech, Inc.
(Exact Name of Registrant as Specified in its Charter)

Table 1: Newly Registered and Carry Forward Securities

	Security Type	Security Class Title	Fee Calculation or Carry Forward Rule	Amount Registered[(1)]	Proposed Maximum Offering Price Per Unit	Maximum Aggregate Offering Price[(2)]	Fee Rate	Amount of Registration Fee[(3)]	Carry Forward Form Type	Carry Forward File Number	Carry Forward Initial effective date	Filing Fee Previously Paid In Connection with Unsold Securities to be Carried Forward
Newly Registered Securities												
Fees Previously Paid	Equity	Common stock par value $0.00001 per share	457(a) and/or (o)	70,849[(4)]	$4.30[(5)]	$304,650.70		$28.24				
Fees Previously Paid	Equity	Common stock par value $0.00001 per share	457(a) and/or (o)	220,997[(6)]	$4.30[(5)]	$950,287.10		$88.09				
Fees Previously Paid	Equity	Common stock par value $0.00001 per share	457(a) and/or (o)	4,972,428[(7)]	$3.12[(8)]	$15,513,975.40		$1,438.15				
Total Offering Amounts								$16,768,913.20				
Total Fees Previously Paid								$1,554.48				
Total Fee Offsets								-				
Net Fee Due								-				

1. This registration statement also relates to such additional shares of Common Stock as may be issued in connection with a stock split, stock dividend, recapitalization, or similar transaction effected without receipt of consideration that increases the number of the registrant's outstanding shares of Common Stock, pursuant to Rule 416 of the Securities Act of 1933, as amended (the "Securities Act").
2. Estimated solely for the purpose of calculating the registration fee under Rule 457(a) and (o) of the Securities Act.
3. Based on the calculation of multiplying the aggregate offering amount by $0.0000927.
4. Consists of 70,849 shares of Common Stock issuable upon exercise of the April 2022 Wainwright Warrants.
5. Estimated solely for the purpose of computing the amount of the registration fee pursuant to Rule *457* under the Securities Act, based on the average of the high and low prices of the Common Stock on the Nasdaq Capital Market on April 26, 2022.
6. Consists of 220,997 shares of Common Stock issuable upon exercise of the August 2022 Wainwright Warrants.
7. Consists of 4,972,428 shares of Common Stock issuable upon exercise of the Preferred Investment Options.
8. Estimated solely for the purpose of computing the amount of the registration fee pursuant to Rule *457* under the Securities Act, based on the average of the high and low prices of the Common Stock on the Nasdaq Capital Market on August 25, 2022.

Table 3: Combined Prospectuses

Security Type	Security Class Title	Amount of Securities Previously Registered(1)	Maximum Aggregate Offering Price of Securities Previously Registered(2)	Form Type	File Number	Initial Effective Date
Equity	Common stock par value $0.00001 per share	70,849(3)	$ 304,650.70	S-1	333-26464	May 20, 2022
Equity	Common stock par value $0.00001 per share	220,997(4)	$ 950,287.10	S-1	333-26464	May 20, 2022
Equity	Common stock par value $0.00001 per share	4,972,428(5)	$ 304,650.70	S-1	333-267142	September 19, 2022

1. This registration statement also relates to such additional shares of Common Stock as may be issued in connection with a stock split, stock dividend, recapitalization, or similar transaction effected without receipt of consideration that increases the number of the registrant's outstanding shares of Common Stock, pursuant to Rule 416 of the Securities Act.
2. Based on the calculation of multiplying the aggregate offering amount by $0.0000927.
3. Consists of 70,849 shares of Common Stock issuable upon exercise of the April 2022 Wainwright Warrants.
4. Consists of 220,997 shares of Common Stock issuable upon exercise of the August 2022 Wainwright Warrants.
5. Consists of 4,972,428 shares of Common Stock issuable upon exercise of the Preferred Investment Options.