As filed with the United States Securities and Exchange Commission on November 4, 2021.
No. 333-260137

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

AMENDMENT NO. 1 TO
FORM S-1
REGISTRATION STATEMENT
UNDER
THE SECURITIES ACT OF 1933

BLUE WATER VACCINES, INC.

(Exact name of registrant as specified in its charter)

Delaware	2834	83-2262816
(State or other jurisdiction of incorporation or organization)	**(Primary Standard Industrial Classification Code Number)**	**(I.R.S. Employer Identification No.)**

201 E. Fifth Street, Suite 1900
Cincinnati, Ohio 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 Vaccines, Inc.
201 E. Fifth Street, Suite 1900
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Copies of all communications, including communications sent to agent for service, should be sent to:

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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, a smaller reporting company, or an emerging growth company. See the definitions of "large accelerated filer," "accelerated filer," "smaller reporting company," and "emerging growth 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 pursuant to Section 7(a)(2)(B) of the Securities Act. ☐

CALCULATION OF REGISTRATION FEE

Title of Each Class of Securities to be Registered	Proposed Maximum Aggregate Offering Price[1]	Amount of Registration Fee[2]
Common Stock, $0.00001 par value per share[3]	$ 23,000,000	$ 2,132.10
Representative's Warrants[4]		
Common Stock issuable upon exercise of Representative's Warrants[5]	$ 1,322,500	$ 122.60
Total	$ 24,322,500	$ 2,254.70[6]

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(1) Estimated solely for the purpose of calculating the amount of the registration fee in accordance with Rule 457(o) under the Securities Act. Includes the offering price of additional shares that the underwriters have the option to purchase to cover over-allotments, if any.

(2) Registration fee will be paid when registration statement is first publicly filed under the Securities Act.

(3) Pursuant to Rule 416 under the Securities Act, the shares registered hereby also include an indeterminate number of additional shares as may from time to time become issuable by reason of stock splits, distributions, recapitalizations, or other similar transactions.

(4) In accordance with Rule 457(g) under the Securities Act, because the shares of the registrant's Common Stock underlying the Representative's warrants are registered hereby, no separate registration fee is required with respect to the warrants registered hereby.

(5) The Warrants are exercisable at a per share exercise price equal to 115% of the public offering price of the shares of Common Stock.

(6) Previously paid.

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 that specifically states that this registration statement shall thereafter become effective in accordance with Section 8(a) of the Securities Act, or until the registration statement shall become effective on such date as the Securities and Exchange Commission, acting pursuant to said section 8(a), may determine.

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The information in this preliminary prospectus is not complete and may be changed. We may not sell these securities 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 it is not soliciting an offer to buy these securities in any state where the offer or sale is not permitted.

SUBJECT TO COMPLETION, DATED NOVEMBER 4, 2021

2,222,222 Shares

Common Stock

This is the initial public offering of our common stock. Prior to this offering there has been no public market for our common stock. We are offering 2,222,222 shares of common stock. We currently expect the initial public offering price to be between $8.00 and $10.00 per share.

We intend to apply to list our common stock on the Nasdaq Capital Market, or Nasdaq, under the symbol "BWV."

We are an "emerging growth company" as that term is defined in the Jumpstart Our Business Startups Act of 2012, or the JOBS Act, and, as such, have elected to take advantage of certain reduced public company reporting requirements for this prospectus and future filings.

Investing in our common stock involves a high degree of risk. Please read "Risk Factors" beginning on page 12 of this prospectus.

	Per Share	Total
Public offering price	$	$
Underwriting discounts and commissions[(1)]	$	$
Proceeds to us, before expenses	$	$

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(1) We have also agreed to reimburse the underwriters for certain expenses incurred by them and the underwriters will receive compensation in addition to underwriting discounts and commissions. See "Underwriting" beginning on page 153 of this prospectus for more information about the compensation payable to the underwriters, including reimbursable expenses.

We have granted to the underwriters an option to purchase up to 333,333 additional shares of common stock at the public offering price, less the underwriting discounts and commissions, for 45 days after the date of this prospectus.

Neither the Securities and Exchange Commission nor any state securities commission has approved or disapproved of these securities or passed upon the adequacy or accuracy of this prospectus. Any representation to the contrary is a criminal offense.

Delivery of the common stock is expected to be made on or about , 2021.

Sole Book Running Manager

Maxim Group LLC

The date of this prospectus is , 2021

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We have not, and the underwriters have not, authorized anyone to provide any information or to make any representations other than those contained in this prospectus or in any free writing prospectus prepared by or on behalf of us or to which we have referred you. We and the underwriters take no responsibility for, and can provide no assurance as to the reliability of, any other information that others may give you. This prospectus is an offer to sell only the shares offered hereby, but only under the circumstances and in the jurisdictions where it is lawful to do so. The information contained in this prospectus or in any applicable free writing prospectus is current only as of its date, regardless of its time of delivery or any sale of our common stock. Our business, financial condition, results of operations and prospects may have changed since that date.

For investors outside the United States: We have not, and the underwriters have not, done anything that would permit this offering or possession or distribution of this prospectus or any applicable free writing prospectus in any jurisdiction where action for that purpose is required, other than in the United States. Persons outside the United States who come into possession of this prospectus and any applicable free writing prospectus must inform themselves, and observe any restrictions relating to, the offering of the common shares and the distribution of this prospectus outside the United States.

Through and including , 202 (25 days after the date of this prospectus), all dealers that buy, sell or trade shares of our common stock, whether or not participating in this offering, may be required to deliver a prospectus. This delivery requirement is in addition to the obligation of dealers to deliver a prospectus when acting as underwriters and with respect to their unsold allotments or subscriptions.

We use our registered trademarks and trade names in this prospectus. This prospectus also includes trademarks, trade names and service marks that are the property of other organizations. Solely for convenience, trademarks and trade names referred to in this prospectus appear without the® and ™ symbols, but those references are not intended to indicate that we will not assert, to the fullest extent under applicable law, our rights, or that the applicable owner will not assert its rights, to these trademarks and trade names. We do not intend our use or display of other companies' trade names or trademarks to imply a relationship with, or endorsement or sponsorship of us by, any other companies.

PROSPECTUS SUMMARY

This summary highlights selected information contained elsewhere in this prospectus, and does not contain all of the information that you should consider before investing in our common stock. This summary is qualified in its entirety by, and should be read in conjunction with, the more detailed information appearing elsewhere in this prospectus. You should read this entire prospectus carefully, including the information set forth in the sections titled "Risk Factors" and "Management's Discussion and Analysis of Financial Condition and Results of Operations" and our financial statements and related notes thereto included elsewhere in this prospectus, before making an investment decision. Unless the context requires otherwise, references in this prospectus to "we," "us," "our," "our company," the "Company" or similar terminology refer to Blue Water Vaccines, Inc. Unless otherwise noted, all share amounts and per share amounts in this prospectus reflect a stock split of the outstanding shares of our Common Stock (following the conversion of our preferred stock) at a ratio of 4:1 to be effected immediately prior to the pricing of this offering. The Pre-IPO Stock Split is subject to approval by our stockholders and Board of Directors. Our financial statements and related notes thereto included elsewhere in this prospectus do not reflect the Pre IPO- Stock Split.

We are a biotechnology company focused on the research and development of transformational vaccines to prevent infectious diseases worldwide. Our versatile vaccine platform has unique molecular properties that enables delivery of various antigens, which can be utilized to develop singular or multi-targeted vaccines. Our lead influenza (flu) vaccine program uses proprietary technology to identify specific epitopes, or proteins, with cross-reactive properties that enables the potential development of a universal flu vaccine. We are focused on developing novel vaccines that induce durable and long-term immunity. 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.

Our pipeline includes novel vaccine candidates exclusively licensed from renowned research institutions. 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 exclusive license agreements include patented influenza epitopes of limited variability, or ELV, identified through a proprietary computational research and discovery process, discovered by Dr. Sunetra Gupta and her team at the University of Oxford. Our collaborators are pioneers in vaccine discovery and development. We are exploring the development of these influenza ELV's 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 our platform to develop a vaccine for the prevention of gastroenteritis cause by both norovirus and rotavirus. Our exclusively licensed *S. pneumoniae* vaccine candidate is from St. Jude Children's Research Hospital. The vaccine is designed to prevent harmful middle-ear infections in children and is being developed for intranasal delivery, well suited for pediatric patients. We leverage the expertise of our collaborators to pursue the discovery and development of vaccines for these diseases, which are 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.

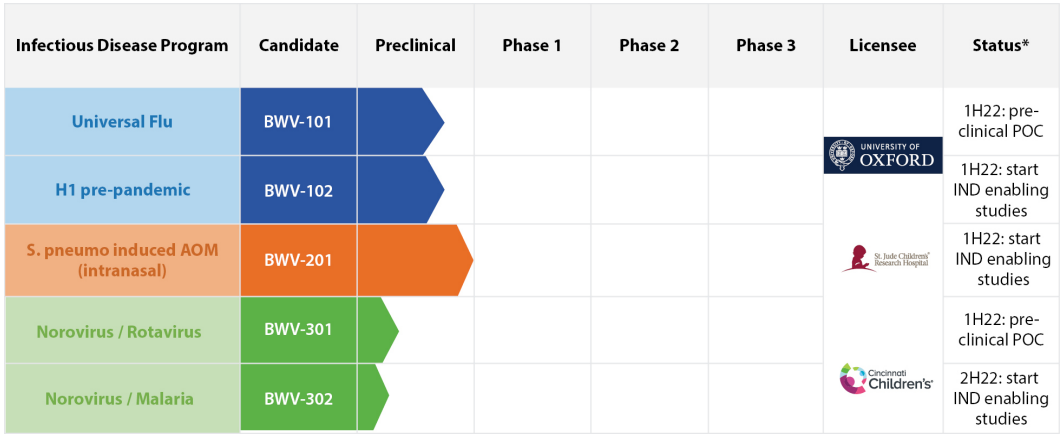
As such, market research professionals project the global vaccine market size to reach $73.78 billion by 2028, representing a CAGR of 7.3% over the forecast period, driven by rising prevalence of infectious diseases, increasing government funding for vaccine production and growing emphasis on becoming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



* Pipeline projections are based upon the completion of the initial public offering.

Our Vaccine Platform

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 we believe supports 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.

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, 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.* The power 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, 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.

Our Vaccine Candidates

BWV-101 and BWV-102: Influenza vaccine program

Our lead vaccine program is focused on developing a transformational novel universal influenza vaccine, BWV-101. This program is licensed from the University of Oxford, where all relevant studies were performed to support our hypothesis. We are developing a broad-spectrum vaccine using patented epitopes of limited variability, or ELV, that provide cross reactive immune response to multiple historical flu strains. Additionally, based upon the successful pre-clinical proof-of-concept (POC) of our H1 epitopes, we are developing a stand-alone H1 influenza vaccine, BWV-102, to provide a long-lasting induced 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. Data in mice models have demonstrated proof of concept of neutralization against historical and current H1 strains, which includes annual and pandemic strains. This would negate annual flu shots, reformulation and potentially provide protection against future influenza pandemics. (Thompson et al. Nature Communications. 2018. 9:385).

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. AOM due to *S. pneumoniae* infections range from 30 to 50% of all AOM infections each year (Monsata 2012 2012; 7(4): e36226). BWV-201 is a live attenuated serotype-independent intranasal vaccine candidate for *S. pneumoniae* induced AOM.

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. Preclinical study results testing our vaccine design are expected in 2022.

Strategy

We aim to identify, discover and develop novel preventive vaccines for infectious diseases. Key elements of our strategy include:

- **Investment in advancing the development of our novel vaccine pipeline programs through IND-enabling activities and Phase I clinical studies.**
    - We plan to advance our main vaccine programs: influenza, *S. pneumoniae* induced AOM norovirus-rotavirus, and norovirus-malaria.
    - Our in-licensed vaccine candidates are carefully selected based on the following criteria: area of significant unmet medical need for preventive long-term vaccine; strong scientific rationale and established clinical and regulatory pathways; defined competitive landscape and potential future commercial opportunity; and license exclusivity.
- **Prioritizing the research and development for our lead influenza vaccine candidates, BWV-101 and BWV-102 through Phase I.**
    - Our goal is to develop a universal influenza vaccine that protects against all strains of influenza, including pandemic strains. In collaboration with The University of Oxford and CHMC, we are evaluating vaccine candidates to pursue the best development path forward to stimulate durable and broad-spectrum immunogenicity.
    - We will leverage the pre-clinical and clinical experience we gain from the development of BWV-102 to accelerate the development of the BWV-101 program. We expect that the manufacturing and clinical data collected will provide invaluable insight for development of the universal vaccine candidate.
- **Maximize and utilize the value of our collaborators and third-party vendors.**
    - We will combine disciplined business strategies to further expand the potential synergies with current collaborators.
- **Deploy and expand our proprietary norovirus S&P nanoparticle platform.**
    - Our immunogenic multi-purpose vaccine platform technologies can be utilized with an array of infectious disease agents to access multiple development pathways and allow for potential next-generation life cycle management to expand our pipeline and pursue business development opportunities. There is potential for the platform to pursue adjunctive therapies to currently available drugs, and for current therapies to be re-optimized and formulated to protect against multiple antigens.

As a preclinical stage biotechnology vaccine company, an investment in us is highly speculative because we have incurred and will incur 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. We estimate that, based on our existing cash as of June 30, 2021, we have cash on hand sufficient to fund our operations into the second quarter of 2022. Our ability to continue as a going concern beyond the second quarter of 2022 is contingent upon obtaining proceeds from this offering. We expect our existing cash as of June 30, 2021 together with proceeds from this offering will enable us to fund our operating expenses and

capital expenditure requirements for at least 12 months from the date of this prospectus. However, we will need to raise additional capital beyond this offering prior to commencing pivotal trials for any of our vaccine candidates. If we cannot continue as a viable entity, our stockholders may lose some or all of their investment in our company.

Management and History

Blue Water Vaccines, Inc. was founded in October 2018 by our Chief Executive Officer, or CEO, Joseph Hernandez, with the initial goal of developing a transformational universal flu vaccine to treat and prevent infections in patients globally. Our initial technology, licensed from the University of Oxford, provides a novel approach to developing a universal influenza vaccine. Subsequently, our team has identified other program candidates and technologies to broaden and diversify our vaccine pipeline.

Mr. Hernandez, our Chairman and CEO, is a veteran entrepreneur, philanthropist, and operator with a broad skillset of founding, building, and selling companies, as well as executing business development transactions and securing private and public capital, including Digene, Noachis Terra and Blue Water Acquisition Corp. Mr. Hernandez was responsible for our initial $7 million seed funding round from investors including CincyTech. In addition to his position as our Chairman and CEO, Mr. Hernandez also serves on the board of directors for Clarus Theraputics, Inc. (Nasdaq: CRXT) in addition to certain other private companies. Subsequently, a team of veteran industry executives and advisors were assembled, bringing valuable expertise to our growing infectious disease company.

Jon Garfield, who will be our Chief Financial Officer upon consummation of the offering, has over 20 years of financial leadership experience, including with healthcare companies. Mr. Garfield regularly provides consulting services to private equity funds and privately held companies and has served as the CEO of Unity MSK since February 2021, and he has served as Interim Chief Financial Officer of Blue Water Vaccines, Inc. since September 2021. Erin Henderson, who serves as our Chief Business Officer, has over 20 years of leading strategic transactions, governmental and stakeholder relations and corporate expansion. Previously, since 2010 she was the Managing Principal at The Aetos Group, a management consulting firm serving both the public and private sectors. Andrew Skibo is our Head of Biologic Operations and was recently Head of Global Biologics Operations at MedImmune/AstraZeneca and previously worked for Amgen and Genentech (now Roche), where he was responsible for operations, engineering, construction, and validation for large-scale capital projects related to bio-pharmaceutical manufacturing. Ronald Cobb, Ph.D., our Head of Science and Discovery, was recently Chief Scientific Officer at Ology Bioservices (formerly Nanotherapeutics) and previously worked for RTI Biologics and Berlex Biosciences. Brian Price, Ph.D., our Head of Technology Strategy, brings over 20 years of successful product development experience and business development growth based on programs in toxicology, analytics, and therapeutic and vaccine development.

Additionally, members of our Board of Directors have extensive expertise in the fields of life sciences, business, and finance. In addition to Mr. Hernandez, our directors upon the consummation of this offering include Michael Venerable, CEO of CincyTech, Kimberly Murphy, former VP, Commercialization Leader, influenza at GlaxoSmithKlein, Allan Shaw, an experienced biotechnology CFO and director nominee James Sapirstein, R.Ph., M.B.A, President and CEO of AzurRx BioPharma (Nasdaq:AZRX).

Our Scientific Advisory Board includes Sunetra Gupta, Ph.D., Professor of Theoretical Epidemiology at The University of Oxford, a leading voice in infectious disease globally; David Zarley, Ph.D., with more than 30 years of experience in vaccine research and development, including former leadership roles at Pfizer and Wyeth; and, following the consummation of this offering, John Rice, Ph.D., Managing Director at CincyTech with more than 30 years of biotechnology advising experience.

Subject to certain non-compete restrictions, our chief executive officer, Joseph Hernandez, our chief financial officer following the offering, Jon Garfield, and other key personnel may pursue other business or investment ventures while employed with us. Accordingly, they may have conflicts of interest in allocating time among various business activities and potentially competitive fiduciary and pecuniary interests that conflict with our interests. See “Risk Factors — Our Chief Executive Officer, Joseph Hernandez, and our Chief Financial Officer, Jon Garfield, hold certain management positions and directorships of other companies and may allocate their time to such other businesses, which may cause conflicts of interest in their determination as to how much time to devote to our affairs and potentially competitive fiduciary and pecuniary interests that conflict with our interests.” For a complete discussion of the business affairs of our officers, directors and other personnel, please see

"Management — Executive Officers and Directors." Any such additional business activities or ventures may present conflicts to our interests. We do not believe that any such potential conflicts would materially affect our ability to conduct our operations.

Implications of Being an Emerging Growth Company

We qualify as an "emerging growth company," as defined in the JOBS Act. For as long as we remain an emerging growth company, we may take advantage of certain exemptions from various reporting requirements that are applicable to other public companies. These provisions include, but are not limited to:

- being permitted to have only two years of audited financial statements and only two years of related selected financial data and management's discussion and analysis of financial condition and results of operations disclosure;
- an exemption from compliance with the auditor attestation requirement in the assessment of our internal control over financial reporting pursuant to Section 404 of the Sarbanes-Oxley Act of 2002, as amended, or the Sarbanes-Oxley Act;
- reduced disclosure about executive compensation arrangements in our periodic reports, registration statements and proxy statements; and
- exemptions from the requirements to seek non-binding advisory votes on executive compensation or golden parachute arrangements.

In addition, the JOBS Act permits emerging growth companies to take advantage of an extended transition period to comply with new or revised accounting standards applicable to public companies. We are not choosing to "opt out" of this provision. We will remain an emerging growth company until the earliest of (i) the last day of the fiscal year following the fifth anniversary of the completion of this offering, (ii) the last day of the first fiscal year in which our annual gross revenues exceed $1.07 billion, (iii) the date on which we have, during the immediately preceding three-year period, issued more than $1.0 billion in non-convertible debt securities and (iv) the end of any fiscal year in which the market value of our common stock held by non-affiliates exceeds $700 million as of the end of the second quarter of that fiscal year. We have elected to take advantage of certain of the reduced disclosure obligations in the registration statement of which this prospectus forms a part and may elect to take advantage of other reduced reporting requirements in future filings. As a result, the information that we provide to our stockholders may be different than you might receive from other public reporting companies in which you hold equity interests.

Summary of Risks Related to Our Business

Our business is subject to a number of risks, including risks that may prevent us from achieving our business objectives or may adversely affect our business, financial condition, results of operations, cash flows and prospects that you should consider before making a decision to invest in our common stock. These risks are discussed more fully in "Risk Factors" beginning on page 12 of this prospectus. These risks include, but are not limited to, the following:

- We are in the early stages of vaccine development and have a very limited operating history and no products approved for commercial sale, 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 or maintain profitability. Our stock is a highly speculative investment.
- There is substantial doubt about our ability to continue as a going concern. Even after this offering, we will require substantial additional funding to finance our operations. We estimate that, based on our existing cash as of June 30, 2021, we have cash on hand sufficient to fund our operations into the second quarter of 2022. Our ability to continue as a going concern beyond the second quarter of 2022 is contingent upon obtaining proceeds from this offering. We expect our existing cash as of June 30, 2021 together with proceeds from this offering will enable us to fund our operating expenses and capital

expenditure requirements for at least 12 months from the date of this prospectus. However, we will need to raise additional capital beyond this offering prior to commencing pivotal trials for any of our vaccine candidates. 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, and we may be unable to continue as a going concern. If we cannot continue as a viable entity, our stockholders may lose some or all of their investment in us.

- Due to the significant resources required for the development of our vaccine candidates, and depending on our ability to access capital, we must prioritize development of certain vaccine candidates. Moreover, we may expend our limited resources on vaccine candidates that do not yield a successful vaccine and fail to capitalize on vaccine candidates that may be more profitable or for which there is a greater likelihood of success.
- We depend entirely 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 successfully commercialize one or more of our product candidates or we experience significant delays in doing so, we may never become profitable.
- The marketing approval process of the U.S. Food and Drug Association, or FDA, is lengthy, time consuming and inherently unpredictable, and if we are ultimately unable to obtain marketing approval for our current product candidates and future product candidates we intend to develop, our business will be substantially harmed.
- The future results of our current or future clinical trials may not support our product candidates' claims or may result in the discovery of unexpected adverse side effects.
- Even if we obtain regulatory approval of our vaccine candidates, the products may not gain market acceptance among regulators, advisory boards, physicians, patients, third-party payors and others in the medical community.
- We may be adversely affected by the ongoing coronavirus pandemic.
- We intend to rely on third parties to conduct our clinical trials and to conduct some aspects of our research and pre-clinical testing and those third parties may not perform satisfactorily, including failing to meet deadlines for the completion of such trials, research or testing.
- Our chief executive officer, chief financial officer and other key personnel may allocate their time to other businesses thereby causing conflicts of interest in their determination as to how much time to devote to our affairs and potentially competitive fiduciary and pecuniary interests that conflict with our interests.
- We may have conflicts with our partners that could delay or prevent the development or commercialization of our current and future product candidates.
- It is difficult and costly to protect our proprietary rights, and we may not be able to ensure their protection. If our patent position does not adequately protect our product candidates, others could compete against us more directly, which would harm our business, possibly materially.
- We are dependent on licensed intellectual property. If we were to lose our rights to licensed intellectual property, we may not be able to continue developing or commercializing our product candidates, if approved. If we breach any of the agreements under which we license the use, development and commercialization rights to our product candidates or technology from third parties or, in certain cases, we fail to meet certain development deadlines, we could lose license rights that are important to our business.
- Some of the intellectual property covered by our licenses concerns patent applications and provisional applications. We cannot assure investors that any of the currently pending or future patent applications will result in granted patents, nor can we predict how long it will take for such patents to be granted.

- If we fail to comply with healthcare regulations, we could face substantial enforcement actions, including civil and criminal penalties and our business, operations and financial condition could be adversely affected.
- Healthcare Reform in the United States has been implemented in the past, and we expect further changes to be proposed in the future, leading to potential uncertainty in the healthcare industry. Violations of healthcare laws can have an adverse impact on our ability to advance our product candidates and our operating results.
- Obtaining regulatory approval for clinical trials of our vaccine candidates in children and adolescents may require additional studies and/or longer duration of studies since the requirements for regulatory approval for the pediatric populations are more stringent.
- The market price of our common stock may be highly volatile, and you could lose all or part of your investment.
- We have broad discretion in the use of the net proceeds from this offering and may invest or spend the proceeds in ways with which you disagree or that may not yield a return.
- Our failure to meet the continued listing requirements of Nasdaq could result in a de-listing of our common stock.
- 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 amended and restated certificate of incorporation ("Amended and Restated Certificate of Incorporation") and our amended and restated bylaws ("Amended and Restated Bylaws") to be adopted in connection with this offering, 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.
- A possible "short squeeze" due to a sudden increase in demand of our common stock that largely exceeds supply may lead to price volatility in our common stock.

Pre-IPO stock split

Immediately prior to the effectiveness of this registration statement, we plan to effect a stock split at a ratio of 4:1, whereby for every share of common stock held (following the conversion of all outstanding shares of series seed preferred stock, pursuant to an optional conversion effective immediately prior to such split, which has been approved by requisite holders of our series seed preferred stock and which conversion will become effective immediately prior to the effectiveness of this registration statement), such holder would own four shares of common stock (the "Pre-IPO Stock Split"). The Pre-IPO Stock Split is subject to approval of our stockholders and Board of Directors. The Pre-IPO Stock Split, based on the shares outstanding as of October 31, 2021, will result in 8,691,576 shares of common stock issued and outstanding immediately prior to the issuance of shares in this offering. See "— The offering" and "Shares eligible for future sale" for more information.

Corporate Information

We were incorporated in Delaware on October 26, 2018. Our principal executive offices are located at 201 E. Fifth Street, Suite 1900, Cincinnati, Ohio 45202, and our telephone number is (513) 620-4101. Our corporate website address is *www.bluewatervaccines.com*. The information contained on or accessible through our website is not a part of this prospectus, and the inclusion of our website address in this prospectus is an inactive textual reference only.

THE OFFERING

Common stock outstanding before this offering	8,691,576 shares, including the conversion of all outstanding shares of convertible preferred stock and accrued dividends into an aggregate of 5,491,576 shares of common stock, pursuant to an optional conversion, effective upon consummation of this offering, which has been approved by requisite holders of our series seed preferred stock.
Common stock offered by us	2,222,222 shares (or 2,555,555 shares if the underwriters exercise the option to purchase additional shares in full).
Common stock to be outstanding after this offering	10,913,798 shares (or 11,247,131 shares if the underwriters exercise the option to purchase additional shares in full).
Option to purchase additional shares	We have granted the underwriters an option for a period of 45 days from the date of this prospectus to purchase an additional 333,333 shares of common stock.
Representative's Warrants	We will issue to Maxim Group LLC, the representative of the several underwriters, or the Representative, upon the closing of this offering, compensation warrants, or the representative's warrants, entitling the Representative to purchase up to 127,778 shares of common stock, representing 5.0% of the aggregate number of shares of common stock issued in this offering, including any shares issued pursuant to the exercise of the underwriters' over-allotment option, at an exercise price per share equal to 115% of the initial public offering price per share. The representative's warrants will have a term of five years from the effective date of the registration statement of which this prospectus forms a part and may be exercised commencing 180 days following the date of commencement of sales of the offering. The representative's warrants may be exercised on a cash or cashless basis. This prospectus also relates to the offering of up to 127,778 shares of common stock issuable upon exercise of the representative's warrants.
Use of proceeds	We currently intend to use the net proceeds from this offering, together with our existing cash and cash equivalents, to fund our research and development activities, clinical trials and the regulatory review process for our product candidates, and the remainder for working capital and other general corporate purposes. See "Use of Proceeds" on page 60.
Lock-up Agreements	We and our directors, officers any other holder(s) of three percent (3.0%) or more of our outstanding shares of common stock have agreed with the representative not to offer for sale, issue, sell, contract to sell, pledge or otherwise dispose of any of our common stock or securities convertible into common stock for a period of six (6) months initial public offering is completed. See "Underwriting" on page 153.
Transfer Agent	Continental Stock Transfer & Trust Company

Risk Factors	See “Risk Factors” on page 12 for a discussion of certain of factors to consider carefully before deciding to purchase any shares of our common stock.
Proposed Nasdaq Capital Market Symbol	“BWV”

The number of shares of our common stock to be outstanding after this offering is based on 8,691,576 shares of common stock outstanding as of October 31, 2021 (after giving effect to (i) the conversion of all outstanding shares of convertible preferred stock and accrued dividends, pursuant to an optional conversion, effective upon consummation of this offering, which has been approved by requisite holders of our series seed preferred stock, into an aggregate of up 5,491,576 shares of common stock and (ii) the Pre-IPO Stock Split), and excludes:

- 780,640 shares of common stock issuable upon the exercise of outstanding stock options under our 2019 Equity Incentive Plan, or the 2019 Plan, as of October 31, 2021, after giving effect to the Pre-IPO Stock Split;
- 619,360 shares of our common stock reserved for future issuance under the 2019 Plan, which, upon adoption of our 2021 Equity Incentive Plan, or the 2021 Plan, will be issuable under the 2021 Plan, after giving effect to the Pre-IPO Stock Split;
- shares of our common stock issuable upon the exercise of the warrant issued to the representative of the underwriters at the closing of this offering.

Unless otherwise indicated, all information contained in this prospectus:

- assumes no exercise by the underwriters of their option to purchase up to 333,333 additional shares of our common stock;
- assumes no exercise of the outstanding stock options described above;
- assumes no exercise of the outstanding warrant described above; and
- does not give effect to the Pre-IPO Stock Split.

SUMMARY FINANCIAL DATA

The following tables set forth a summary of our historical financial data as of, and for the periods ended on, the dates indicated. The statements of operations data for the years ended December 31, 2020 and 2019 and balance sheet data as of December 31, 2020 and December 31, 2019 are derived from our audited financial statements included elsewhere in this prospectus. The statements of operations data for the six months ended June 30, 2021 and 2020 and the balance sheet data as of June 30, 2021 are derived from our unaudited financial statements included elsewhere in this prospectus. The unaudited financial statements were prepared on the same basis as the audited financial statements. Our management believes that the unaudited financial statements reflect all adjustments necessary for the fair presentation of the financial condition and results of operations for such periods.

The following summary financial information, which does not reflect the Pre-IPO Stock Split, should be read in connection with, and is qualified by reference to, our financial statements related notes thereto and the section titled "Management's Discussion and Analysis of Financial Condition and Results of Operations" included elsewhere in this prospectus. Our historical results are not necessarily indicative of results to be expected in any future period.

Statement of Operations Data:

	Six months ended June 30, 2021	Six months ended June 30, 2020	Year Ended December 31, 2020	Year Ended December 31, 2019
	(Unaudited)	(Unaudited)		
Operating costs and expenses				
General and administrative	$ 500,276	$ 559,775	$ 1,097,161	$ 820,058
Research and development	617,779	320,336	524,908	60,174
Total operating expenses	1,118,055	880,111	1,622,069	880,232
Loss from operations	(1,118,055)	(880,111)	(1,622,069)	(880,232)
Other income				
Interest income	—	19,431	22,603	58,317
Total other income	—	19,431	22,603	58,317
Net loss	$ (1,118,055)	$ (860,680)	$ (1,599,466)	$ (821,915)
Cumulative preferred stock dividends	276,904	278,434	559,928	279,964
Net loss applicable to common stockholders	$ (1,394,959)	$ (1,139,114)	$ (2,159,394)	$ (1,101,879)
Net loss per share attributable to common stockholders, basic and diluted	$ (1.74)	$ (1.42)	$ (2.70)	$ (1.38)
Weighted average number of common shares outstanding, basic and diluted	800,000	800,000	800,000	800,000

Balance Sheet Data:

	June 30, 2021 (Unaudited)	December 31, 2020	December 31, 2019
Cash	$ 3,669,468	$ 4,308,821	$ 6,050,751
Working capital	$ 3,586,704	$ 4,527,811	$ 5,983,327
Total assets	$ 4,182,719	$ 4,812,080	$ 6,081,020
Total liabilities	$ 490,359	$ 78,310	$ 82,621
Preferred stock	$ 11	$ 11	$ 11
Common stock	$ 8	$ 8	$ 8
Additional paid-in-capital	$ 7,349,732	$ 7,273,087	$ 6,938,250
Accumulated deficit	$ (3,657,391)	(2,539,336)	(939,870)
Total stockholders' equity	$ 3,692,360	$ 4,733,770	$ 5,998,399

RISK FACTORS

Investing in our common stock involves a high degree of risk. You should carefully consider the following information about these risks, together with the other information appearing elsewhere in this prospectus, including our financial statements, the notes thereto and the section entitled "Management's Discussion and Analysis of Financial Condition and Results of Operations," before deciding to invest in our common stock. The occurrence of any of the following risks could have a material adverse effect on our business, reputation, financial condition, results of operations and future growth prospects, as well as our ability to accomplish our strategic objectives. As a result, the trading price of our common stock could decline and you could lose all or part of your investment. Additional risks and uncertainties not presently known to us or that we currently deem immaterial may also impair our business operations and stock price.

Risks Related to our Financial Position and Need for Capital

We are in the early stages of vaccine development and have a very limited operating history and no products approved for commercial sale, 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 four 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 losses were $1.6 million and $0.8 million for the years ended December 31, 2020 and 2019, respectively, and $1.1 million and $0.9 million for the six months ended June 30, 2021 and 2020, respectively. As of June 30, 2021, we had an accumulated deficit of $3.7 million.

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.

Even after this offering, 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 June 30, 2021, we had cash and cash equivalents of $3.7 million. We believe that the net proceeds from this offering will be approximately $17.5 million, based on an assumed public offering price of $9.00 per share, which is the midpoint of the estimated price range set forth on the cover page of this prospectus, after deducting the estimated underwriting discounts and commissions and estimated offering expenses payable by us. We believe that such proceeds, together with our existing cash and cash equivalents as of the date of this prospectus, will fund our current operating plans through at least the next 12 months from the date of this offering. Accordingly, we believe that we will need to raise substantial additional capital to fund our continuing operations and the development and commercialization of our current product candidates and future product candidates. Our business or operating plan may change as a result of many factors currently unknown to us, and we may need to seek additional funds sooner than planned. We will need to raise additional capital before we can progress any of our vaccine candidates into a pivotal clinical trial. We expect to finance our subsequent 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.

However, we may not be able to secure funding when we need it or on favorable terms and we may not be able to raise sufficient funds to commercialize our current and future product candidates we intend to develop. 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, 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.

We may consider strategic alternatives in order to maximize stockholder value, including financings, strategic alliances, licensing arrangements, acquisitions or the possible sale of our business. We may not be able to identify or consummate any suitable strategic alternatives and any consummated strategic alternatives may have an adverse impact on our vaccine candidates.

We may consider all strategic alternatives that may be available to us to maximize stockholder value, including financings, strategic alliances, licensing arrangements, acquisitions or the possible sale of our business. We currently have no agreements or commitments to engage in any specific strategic transactions, and our exploration of various strategic alternatives may not result in any specific action or transaction. To the extent that this engagement results in a transaction, our business objectives may change depending upon the nature of the transaction. There can be no assurance that we will enter into any transaction as a result of the engagement. Furthermore, if we determine to engage in a strategic transaction, we cannot predict the impact that such strategic transaction might have on our operations or stock price. We also cannot predict the impact on our stock price if we fail to enter into a transaction.

In addition, we face significant competition in seeking appropriate strategic partners, and the negotiation process is time-consuming and complex. Moreover, we may not be successful in our efforts to establish a strategic partnership or other alternative arrangements for our vaccine candidates because they may be deemed to be at too early of a stage of development for collaborative effort, and third parties may not view our vaccine candidates as having the requisite potential to demonstrate safety and efficacy. Any delays in entering into new strategic partnership agreements related to our vaccine candidates could delay the development and commercialization of our vaccine candidates in certain geographies for certain indications, which would harm our business prospects, financial condition and results of operations.

If we license products or businesses, we may not be able to realize the benefit of such transactions if we are unable to successfully integrate them with our existing operations and company culture. We cannot be certain that, following a strategic transaction or license, we will achieve the results, revenue or specific net income that justifies such transaction.

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.

Due to the significant resources required for the development of our vaccine candidates, and depending on our ability to access capital, we must prioritize development of certain vaccine candidates. Moreover, we may expend our limited resources on vaccine candidates that do not yield a successful vaccine and fail to capitalize on vaccine candidates that may be more profitable or for which there is a greater likelihood of success.

Due to the significant resources required for the development of our vaccine candidates, we must decide which vaccine candidates to pursue and advance and the amount of resources to allocate to each. Our decisions concerning the allocation of research, development, management and financial resources toward particular vaccine candidates may not lead to the development of any viable commercial vaccines and may divert resources away from better opportunities. Similarly, our potential decisions to delay, terminate, license or collaborate with third parties in respect of certain vaccine candidates may subsequently also prove to be less than optimal and could cause us to miss valuable opportunities. If we make incorrect determinations regarding the viability or market potential of any of our vaccine candidates or misread trends in the biopharmaceutical industry, in particular for vaccines, our business could be seriously harmed. As a result, we may fail to capitalize on viable commercial products or profitable market opportunities, be required to forego or delay pursuit of opportunities with other vaccine candidates that may later prove to have greater commercial potential than those we choose to pursue or relinquish valuable rights to such vaccine candidates through collaboration, licensing or other royalty arrangements in cases in which it would have been advantageous for us to invest additional resources to retain sole development and commercialization rights.

There is substantial doubt about our ability to continue as a going concern.

As of December 31, 2020, December 31, 2019, and June 30, 2021, we had cash of $4.3 million, $6.1 million, and $3.7 million, respectively. In addition, we had current liabilities of approximately $0.5 million as of June 30, 2021. We estimate that, based on our existing cash as of June 30, 2021, we have cash on hand sufficient to fund our operations into the second quarter of 2022. Our ability to continue as a going concern beyond the second quarter of 2022 is contingent upon obtaining proceeds from this offering. We expect our existing cash as of June 30, 2021 together with proceeds from this offering will enable us to fund our operating expenses and capital expenditure requirements for at least 12 months from the date of this prospectus. However, we will need to raise additional capital beyond this offering prior to commencing pivotal trials for any of our vaccine candidates. Until we can generate a sufficient amount of revenue from the commercialization of our vaccine candidates or from collaboration agreements with third parties, if ever, we expect to finance our future 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 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. Similarly, the report of our independent registered public accounting firm on our financial statements as of and for the year ended December 31, 2020 includes an explanatory paragraph indicating that there is substantial doubt about our ability to continue as a going concern. If we cannot continue as a viable entity, our stockholders may lose some or all of their investment in 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.

As a public company, we will be 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. 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 not currently required to comply with the SEC rules that implement Section 404 of the Sarbanes-Oxley Act, and are therefore not required to make a formal assessment of the effectiveness of our internal control over financial reporting for that purpose. As a public company, we will be required to provide an annual management report on the effectiveness of our internal control over financial reporting commencing with our second 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.

Our ability to use our net operating loss carryforwards and certain other tax attributes may be limited, each of which could harm our business.

As of December 31, 2020, we had U.S. federal and state net operating loss carryforwards of approximately $2.1 million. Under Sections 382 and 383 of the Internal Revenue Code, or the Code, if a corporation undergoes an “ownership change,” the corporation’s ability to use its pre-ownership change net operating loss carryforwards and other pre-ownership change tax attributes, such as research tax credits, to offset its post-ownership change income and taxes may be limited. In general, an ownership change will occur when the percentage of the Corporation’s ownership (by value) of one or more “5-percent stockholders” (as defined in the Code) has increased by more than 50 percent over the lowest percentage owned by such stockholders at any time during the prior three years (calculated on a rolling basis). Similar rules may apply under state tax laws. An entity that experiences an ownership change generally will be subject to an annual limitation on its pre-ownership change tax loss and credit carryforwards equal to the equity value of the corporation immediately before the ownership change, multiplied by the long-term, tax-exempt rate posted monthly by the U.S. Internal Revenue Service (subject to certain adjustments). The annual limitation would be increased each year to the extent that there is an unused limitation in a prior year. In the event that it is determined that we have in the past experienced an ownership change as a result of transactions in our stock, or if we experience one or more ownership changes as a result of future transactions in our stock, then we

may be limited in our ability to use our net operating loss carryforwards and other tax assets to reduce taxes owed on the net taxable income that we earn. Any limitations on the ability to use our net operating loss carryforwards and other tax assets could harm our business.

Risks Related to the Development of our Product Candidates

We depend entirely 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 successfully commercialize one or more of our product candidates or we experience significant delays in doing so, we may never become profitable.

We do not have any products that have received regulatory approval and may never be able to develop marketable product candidates. 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.

The marketing approval process of the FDA is lengthy, time consuming and inherently unpredictable, and if we are ultimately unable to obtain marketing approval for our current product candidates and future product candidates we intend to develop, our business will be substantially harmed.

We are at a very early stage of development for all of our product candidates. The product candidates we intend to develop have not gained marketing approval in the U.S., and we cannot guarantee that we will ever have marketable products. Our business is substantially dependent on our ability to complete the development of, obtain marketing approval for, and successfully commercialize our current and future product candidates in a timely manner. We cannot commercialize our product candidates in the United States without first obtaining approval from the FDA to market each product candidate. Our product candidates could fail to receive marketing approval for many reasons, including among others:

- the FDA may disagree with the design or implementation of our clinical trials;
- Our clinical trials for our product candidate(s) must be successful if we are to seek and obtain regulatory marketing application through the submission of a new Biological License Application (BLA) and marketing authorization application (MAA) with the U.S. Food and Drug Administration (FDA) and the European Medicines Agency (EMA), respectively. Advanced clinical trials are often not successful even if prior trials were successful, and even if we are able to conduct advanced clinical trials and those trials are successful, we may not obtain necessary regulatory approvals for our product candidate(s) or we may be unable to successfully commercialize our products even if we receive the necessary regulatory approvals

In addition, the process of seeking regulatory approval to market the product candidates we intend to develop is expensive and time consuming and, notwithstanding the effort and expense incurred, approval is never guaranteed. If we are not successful in obtaining timely approval of our product candidates from the FDA, we may never be able to generate significant revenue and may be forced to cease operations. The new Biological License Application, or BLA, process is costly, lengthy and uncertain. Any BLA application filed by us will have to be supported by extensive data, including, but not limited to, technical, pre-clinical, clinical, manufacturing and labeling data, to demonstrate to the FDA's satisfaction the safety and efficacy of the product for its intended use.

In order to commence a clinical trial in the United States, we will be required to seek FDA acceptance of an IND for each of our product candidates. We cannot be sure any IND we submit to the FDA, or any similar clinical trial application we submit in other countries, will be accepted. If we will be required by regulatory authorities to conduct additional preclinical testing prior to filing an IND or similar application to clinically evaluate any of our product candidates, this may result in delay in our product candidate development. The results of any such preclinical testing may not be positive and may not support an application to study any of our product candidates in additional clinical trials.

It is possible that the FDA or EMA will not view our ongoing or planned trials as providing adequate support for future clinical trials or for an application for marketing approval, for any one or more reasons, including elements of the design or execution of the trials or safety concerns or other trial results. If we are unable to confirm or replicate the results of our trials in larger patient group or if negative results are obtained, we would likely be further delayed or prevented from advancing further clinical development any of our product candidates.

Additionally, the FDA or EMA may disagree with the sufficiency of our proposed reliance upon the preclinical, manufacturing or clinical data generated by third-party academic-sponsored trials, or our interpretation of preclinical, manufacturing or clinical data from our ongoing trials. If so, the FDA or EMA may require us to obtain and submit additional preclinical, manufacturing or clinical data.

Obtaining approvals from the FDA and from the regulatory agencies in other countries is an expensive and time-consuming process and is uncertain as to outcome. The FDA and other agencies could ask us to supplement our submissions, collect non-clinical data, conduct additional clinical trials or engage in other time-consuming actions, or it could simply deny our applications. In addition, even if we obtain a BLA approval or pre-market approvals in other countries, the approval could be revoked or other restrictions imposed if post-market data demonstrate safety issues or lack of effectiveness. We cannot predict with certainty how, or when, the FDA will act. If we are unable to obtain the necessary regulatory approvals, our financial condition and cash flow may be adversely affected,

and our ability to grow domestically and internationally may be limited. Additionally, even if cleared or approved, our products may not be approved for the specific indications that are most necessary or desirable for successful commercialization or profitability.

We may encounter substantial delays in completing our clinical studies which in turn will require additional costs, or we may fail to demonstrate adequate safety and efficacy to the satisfaction of applicable regulatory authorities.

It is impossible to predict if or when our current or future product candidates, will prove safe or effective in humans or will receive regulatory approval. Before obtaining marketing approval from regulatory authorities for the sale of our product candidates, we must conduct extensive clinical studies to demonstrate the safety and efficacy of the product candidates in humans. Clinical testing is expensive, time-consuming and uncertain as to outcome. We cannot guarantee that any clinical studies will be conducted as planned or completed on schedule, if at all. A failure of one or more clinical studies can occur at any stage of testing. Events that may prevent successful or timely completion of clinical development include:

- delays in reaching, or failing to reach, a consensus with regulatory agencies on study design;
- delays in reaching, or failing to reach, agreement on acceptable terms with a sufficient number of prospective contract research organizations, or CROs, and clinical study sites, the terms of which can be subject to extensive negotiation and may vary significantly among different CROs and trial sites;
- delays in recruiting a sufficient number of suitable patients to participate in our clinical studies;
- imposition of a clinical hold by regulatory agencies, after an inspection of our clinical study operations or study sites;
- failure by our CROs, other third parties or us to adhere to clinical study, regulatory or legal requirements;
- failure to perform in accordance with the FDA's good clinical practices, or GCPs, or applicable regulatory guidelines in other countries;
- delays in the testing, validation, manufacturing and delivery of sufficient quantities of our product candidates to the clinical sites;
- delays in having patients complete participation in a study or return for post-treatment follow-up;
- clinical study sites or patients dropping out of a study;
- delay or failure to address any patient safety concerns that arise during the course of a trial;
- unanticipated costs or increases in costs of clinical trials of our product candidates;
- occurrence of serious adverse events associated with the product candidates that are viewed to outweigh its potential benefits; or
- changes in regulatory requirements and guidance that require amending or submitting new clinical protocols.

We could also encounter delays if a clinical trial is suspended or terminated by us, by the Institutional Review Board, or IRB, or the Ethics Commission of the institutions in which such trials are being conducted, by an independent Safety Review Board, or SRB, for such trial or by the FDA or other regulatory authorities. Such authorities may suspend or terminate a clinical trial due to a number of factors, including failure to conduct the clinical trial in accordance with regulatory requirements or our clinical protocols, inspection of the clinical trial operations or trial site by the FDA or other regulatory authorities resulting in the imposition of a clinical hold, unforeseen safety issues or adverse side effects, failure to demonstrate a benefit from using a drug, changes in governmental regulations or administrative actions or lack of adequate funding to continue the clinical trial.

Any inability to successfully complete pre-clinical and clinical development could result in additional costs to us or impair our ability to generate revenues from product sales, regulatory and commercialization milestones and royalties. In addition, if we make manufacturing or formulation changes to our product candidates, we may need to conduct additional studies to bridge our modified product candidates to earlier versions.

Clinical study delays could also shorten any periods during which we may have the exclusive right to commercialize our product candidates or allow our competitors to bring products to market before we do, which could impair our ability to successfully commercialize our product candidates. In addition, any delays in completing our clinical trials will increase our costs, slow down our product candidates' development and approval process and jeopardize our ability to commence product sales and generate revenues. Any of these occurrences may significantly harm our business, financial condition and prospects. In addition, many of the factors that cause, or lead to, a delay in the commencement or completion of clinical trials may also ultimately lead to the denial of regulatory approval of our product candidates.

The outcome of pre-clinical studies and early clinical trials may not be predictive of the success of later clinical trials, and interim results of a clinical trial do not necessarily predict final results. Further, pre-clinical and clinical data are often susceptible to various interpretations and analyses, and many companies that have believed their product candidates performed satisfactorily in pre-clinical studies and clinical trials have nonetheless failed to obtain marketing approval. If the results of our clinical studies are inconclusive or if there are safety concerns or adverse events associated with our product candidates, we may:

- be delayed in obtaining marketing approval for our product candidates, if approved at all;
- obtain approval for indications or patient populations that are not as broad as intended or desired;
- obtain approval with labeling that includes significant use or distribution restrictions or safety warnings;
- be required to change the way the product is administered;
- be required to perform additional clinical studies to support approval or be subject to additional post-marketing testing requirements;
- have regulatory authorities withdraw their approval of a product or impose restrictions on its distribution in the form of a modified risk evaluation and mitigation strategy;
- be sued; or
- experience damage to our reputation.

Additionally, our product candidates could potentially cause other adverse events that have not yet been predicted. The inclusion of ill patients in our clinical studies may result in deaths or other adverse medical events due to other therapies or medications that such patients may be using. As described above, any of these events could prevent us from achieving or maintaining market acceptance of our product candidates and impair our ability to commercialize our products.

Obtaining and maintaining regulatory approval of our vaccine candidates in one jurisdiction does not mean that we will be successful in obtaining regulatory approval of our vaccine candidates in other jurisdictions.

Obtaining and maintaining regulatory approval of our vaccine candidates in one jurisdiction does not guarantee that we will be able to obtain or maintain regulatory approval in any other jurisdiction, while a failure or delay in obtaining regulatory approval in one jurisdiction may have a negative effect on the regulatory approval process in others. For example, even if the FDA grants marketing approval of a vaccine candidate, comparable regulatory authorities in foreign jurisdictions must also approve the manufacturing, marketing and promotion of the vaccine candidate in those countries. Approval procedures vary among jurisdictions and can involve requirements and administrative review periods different from, and greater than, those in the United States, including additional preclinical studies or clinical trials as clinical studies conducted in one jurisdiction may not be accepted by regulatory authorities in other jurisdictions. In many jurisdictions outside the United States, a vaccine candidate must be approved for reimbursement before it can be approved for sale in that jurisdiction. In some cases, the price that we intend to charge for our products is also subject to approval.

We may also submit marketing applications in other countries. Regulatory authorities in jurisdictions outside of the United States have requirements for approval of vaccine candidates with which we must comply prior to marketing in those jurisdictions. Obtaining foreign regulatory approvals and compliance with foreign regulatory requirements could result in significant delays, difficulties and costs for us and could delay or prevent

the introduction of our products in certain countries. If we fail to comply with the regulatory requirements in international markets and/or receive applicable marketing approvals, our target market will be reduced and our ability to realize the full market potential of our vaccine candidates will be harmed.

Modifications to our products may require new BLA approvals.

Once a particular product receives FDA approval, expanded uses or uses in new indications of our products may require additional human clinical trials and new regulatory approvals, including additional IND and BLA submissions and premarket approvals before we can begin clinical development, and/or prior to marketing and sales. If the FDA requires new approvals for a particular use or indication, we may be required to conduct additional clinical studies, which would require additional expenditures and harm our operating results. If the products are already being used for these new indications, we may also be subject to significant enforcement actions. Conducting clinical trials and obtaining approvals can be a time-consuming process, and delays in obtaining required future approvals could adversely affect our ability to introduce new or enhanced products in a timely manner, which in turn would harm our future growth.

Additional delays to the completion of clinical studies may result from modifications being made to the protocol during the clinical trial, if such modifications are warranted and/or required by the occurrences in the given trial.

Each modification to the protocol during a clinical trial has to be submitted to the FDA. This could result in the delay or halt of a clinical trial while the modification is evaluated. In addition, depending on the quantity and nature of the changes made, the FDA could take the position that the data generated by the clinical trial are not poolable because the same protocol was not used throughout the trial. This might require the enrollment of additional subjects, which could result in the extension of the clinical trial and the FDA delaying approval of a product. Any such delay could have a material adverse effect on our business and results of operations.

There can be no assurance that the data generated from our clinical trials using modified protocols will be acceptable to the FDA or other regulatory authorities.

There can be no assurance that the data generated using modified protocols will be acceptable to the FDA or other regulatory authorities or that if future modifications during the trial are necessary, that any such modifications will be acceptable to the FDA or other regulatory authorities. If the FDA or other regulatory authorities believe that prior approval is required for a particular modification, they can delay or halt a clinical trial while they evaluate additional information regarding the change.

Serious injury or death resulting from a failure of our product candidates during current or future clinical trials could also result in the FDA or other regulatory authority delaying our clinical trials or denying or delaying approval of a product.

Even though an adverse event may not be the result of the failure of our product candidate, the FDA or other regulatory authority could delay or halt a clinical trial for an indefinite period of time while an adverse event is reviewed, and likely would do so in the event of multiple such events.

Any delay or termination of our current or future clinical trials as a result of the risks summarized above, including delays in obtaining or maintaining required approvals from the FDA or other regulatory authorities, delays in patient enrollment, the failure of patients to continue to participate in a clinical trial, and delays or termination of clinical trials as a result of protocol modifications or adverse events during the trials, may cause an increase in costs and delays in the filing of any product submissions with the FDA or other regulatory authorities, delay the approval and commercialization of our products or result in the failure of the clinical trial, which could adversely affect our business, operating results and prospects.

We will depend on enrollment and retention of patients in our clinical trials for our product candidates. If we experience delays or difficulties enrolling or retaining patients in our clinical trials, our research and development efforts and business, financial condition, and results of operations could be materially adversely affected.

Successful and timely completion of clinical trials will require that we enroll and retain a sufficient number of patient candidates. Any clinical trials we conduct may be subject to delays for a variety of reasons, including as a result of patient enrollment taking longer than anticipated, patient withdrawal, or adverse events. These types of developments could cause us to delay the trial or halt further development.

Our clinical trials will compete with other clinical trials that are in the same therapeutic areas as our product candidates, and this competition reduces the number and types of patients available to us, as some patients who might have opted to enroll in our trials may instead opt to enroll in a trial being conducted by one of our competitors. Moreover, enrolling patients in clinical trials for diseases in which there is an approved standard of care is challenging, as patients will first receive the applicable standard of care. Many patients who respond positively to the standard of care do not enroll in clinical trials. This may limit the number of eligible patients able to enroll in our clinical trials who have the potential to benefit from our product candidates and could extend development timelines or increase costs for these programs. Patients who fail to respond positively to the standard of care treatment will be eligible for clinical trials of unapproved drug candidates. However, these prior treatment regimens may render our therapies less effective in clinical trials.

Because the number of qualified clinical investigators and clinical trial sites is limited, we expect to conduct some of our clinical trials at the same clinical trial sites that some of our competitors use, which will reduce the number of patients who are available for our clinical trials at such clinical trial sites.

Patient enrollment depends on many factors, including:

- the size and nature of the patient population;
- the severity of the disease, condition or infection under investigation;
- eligibility criteria for the trial;
- the proximity of patients to clinical sites;
- the design of the clinical protocol;
- the ability to obtain and maintain patient consents;
- perceived risks and benefits of the product candidate under evaluation;
- the ability to recruit clinical trial investigators with the appropriate competencies and experience;
- the risk that patients enrolled in clinical trials will drop out of the trials before the administration of our product candidates or trial completion;
- the availability of competing clinical trials;
- the availability of such patients during the COVID-19 pandemic;
- the availability of new drugs approved for the indication the clinical trial is investigating; and
- clinicians’ and patients’ perceptions as to the potential advantages of the drug being studied in relation to other available therapies.

These factors may make it difficult for us to enroll enough patients to complete our clinical trials in a timely and cost-effective manner. Delays in the completion of any clinical trial of our product candidates will increase our costs, slow down our product candidate development and approval process, and delay or potentially jeopardize our ability to commence product sales and generate revenue. In addition, some of the factors that cause, or lead to, a delay in the commencement or completion of clinical trials may also ultimately lead to the denial of regulatory approval of our product candidates.

Conducting successful clinical studies may require the enrollment of large numbers of patients, and suitable patients may be difficult to identify and recruit.

Patient enrollment in clinical trials and completion of patient participation and follow-up depends on many factors, including the size of the patient population; the nature of the trial protocol; the attractiveness of, or the discomforts and risks associated with, the treatments received by enrolled subjects; the availability of appropriate clinical trial investigators; support staff; and the proximity of patients to clinical sites and ability to comply with the eligibility and exclusion criteria for participation in the clinical trial and patient compliance. For example, patients may be discouraged from enrolling in our clinical trials if the trial protocol requires them to undergo extensive post-treatment procedures or follow-up to assess the safety and effectiveness of our products or if they determine that the treatments received under the trial protocols are not attractive or involve unacceptable risks or discomforts. Patients may also not participate in our clinical trials if they choose to participate in contemporaneous clinical trials of competitive products.

The future results of our current or future clinical trials may not support our product candidates' claims or may result in the discovery of unexpected adverse side effects.

Even if our clinical trials are completed as planned, we cannot be certain that their results will support our product candidates claims or that the FDA or foreign authorities will agree with our conclusions regarding them. Success in pre-clinical studies and early clinical trials does not ensure that later clinical trials will be successful, and we cannot be sure that the later trials will replicate the results of prior trials and pre-clinical studies. The clinical trial process may fail to demonstrate that our product candidates are safe and effective for the proposed indicated uses. If the FDA concludes that the clinical trials for any product for which we might seek approval, has failed to demonstrate safety and effectiveness, we would not receive FDA approval to market that product in the United States for the indications sought.

In addition, such an outcome could cause us to abandon a product candidate and might delay development of others. Any delay or termination of our clinical trials will delay the filing of any product submissions with the FDA and, ultimately, our ability to commercialize our product candidates and generate revenues. It is also possible that patients enrolled in clinical trials will experience adverse side effects that are not currently part of our product candidate's profile.

Adverse events involving our products may lead the FDA or other regulatory authorities to delay or deny approval for our products or result in product recalls that could harm our reputation, business and financial results.

Additionally, if any of our product candidates receives marketing approval, the FDA could require us to adopt a Risk Evaluation and Mitigation Strategy, or REMS, and other non-U.S. regulatory authorities could impose other specific obligations as a condition of approval to ensure that the benefits outweigh its risks, which may include, among other things, a medication guide outlining the risks of the product for distribution to patients, a communication plan to health care practitioners, and restrictions on how or where the product can be distributed, dispensed or used. Furthermore, if we or others later identify undesirable side effects caused by any of our product candidates, several potentially significant negative consequences could result, including:

- regulatory authorities may suspend or withdraw approvals of such a product candidate;
- regulatory authorities may require additional warnings or limitations of use in product labeling;
- we may be required to change the way a product candidate is distributed, dispensed, or administered or conduct additional clinical trials;
- we could be sued and held liable for harm caused to patients; and
- our reputation may suffer.

Any of these events could prevent us from achieving or maintaining market acceptance of our product candidates and could significantly harm our business, prospects, financial condition and results of operations.

Once a product receives FDA approval, the agency has the authority to require the recall of commercialized products in the event of adverse side effects, material deficiencies or defects in design or manufacture. The authority to require a recall must be based on an FDA finding that there is a reasonable probability that the product would

cause serious injury or death. Manufacturers may, under their own initiative, recall a product if any material deficiency in a product is found. A government-mandated or voluntary recall by us or one of our distributors could occur as a result of adverse side effects, impurities or other product contamination, manufacturing errors, design or labeling defects or other deficiencies and issues. Recalls of any of our products would divert managerial and financial resources and have an adverse effect on our financial condition and results of operations. The FDA requires that certain classifications of recalls be reported to FDA within ten working days after the recall is initiated. Companies are required to maintain certain records of recalls, even if they are not reportable to the FDA. We may initiate voluntary recalls involving our products in the future. A future recall announcement could harm our reputation with customers and negatively affect our sales. In addition, the FDA and/or other regulatory agencies could take enforcement action for failing to report the recalls when they were conducted.

Even if we obtain regulatory approval of our vaccine candidates, the products may not gain market acceptance among regulators, advisory boards, physicians, patients, third-party payors and others in the medical community.

Even if any of our vaccine candidates receive marketing approval, they may fail to receive recommendations for use by regulators or advisory boards that recommend vaccines, or gain market acceptance by physicians, patients, third-party payors and others in the medical community. If such vaccine candidates do not achieve an adequate level of acceptance, we may not generate significant product revenue and may not become profitable. The degree of market acceptance of any vaccine candidate, if approved for commercial sale, will depend on a number of factors, including but not limited to:

- receiving CDC and ACIP recommendations for use, as well as recommendations of comparable foreign regulatory and advisory bodies;
- prevalence and severity of the disease targets for which our vaccine candidates are approved;
- physicians, hospitals, third-party payors and patients considering our vaccine candidates as safe and effective;
- the potential and perceived advantages of our vaccine candidates over existing vaccines, including with respect to spectrum coverage or immunogenicity;
- the prevalence and severity of any side effects;
- product labeling or product insert requirements of the FDA or comparable foreign regulatory and advisory bodies;
- limitations or warnings contained in the labeling approved by the FDA or comparable foreign regulatory and advisory bodies;
- the timing of market introduction of our vaccine candidates as well as competitive products;
- the cost of treatment in relation to alternative treatments;
- the availability of coverage and adequate reimbursement and pricing by third-party payors, including government authorities;
- the willingness of patients to pay out-of-pocket in the absence of coverage and adequate reimbursement by third-party payors, including government authorities;
- relative convenience and ease of administration, including as compared to competitive vaccines and alternative treatments; and
- the effectiveness of our sales and marketing efforts.

In the United States, the CDC and ACIP develop vaccine recommendations for both children and adults, as do similar agencies around the world. To develop its recommendations, ACIP forms working groups that gather, analyze and prepare scientific information. The ACIP also considers many of the factors above, as well as myriad additional factors such as the value of vaccination for the target population regarding the outcomes, health economic data and implementation issues. ACIP recommendations are also made within categories, such as in an age group

or a specified risk group. For example, the ACIP may determine that a preferred recommendation in a smaller child population may be more economical than recommending vaccinations for a larger adult population, which could adversely impact our market opportunity.

New pediatric vaccines that receive an ACIP preferred recommendation are almost universally adopted, and adult vaccines that receive a preferred recommendations are widely adopted. For example, in 2014, the ACIP voted to recommend Prevnar 13 for routine use to help protect adults ages 65 years and older against pneumococcal disease, which caused Prevnar 13 to become the standard of care along with continued use of Pneumovax 23. ACIP can also modify its preferred recommendation. For instance, in June 2019, the ACIP voted to revise the pneumococcal vaccination guidelines and recommend Prevnar 13 for adults 65 and older based on the shared clinical decision making of the provider and patient, rather than a preferred use recommendation, which means the decision to vaccinate should be made at the individual level between health care providers and their patients. Pfizer recently noted that this revised recommendation is expected to have a negative effect on Prevnar 13 revenue for future periods.

If our vaccine candidates are approved but fail to receive CDC and ACIP recommendations, or recommendations of other comparable foreign regulatory and advisory bodies, or achieve market acceptance among physicians, healthcare providers, patients, third-party payors or others in the medical community, we will not be able to generate significant revenue. Even if our products 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 our products, are more cost effective or render our products obsolete.

Obtaining regulatory approval for clinical trials of our vaccine candidates in children and adolescents may require additional studies and/or longer duration of studies since the requirements for regulatory approval for the pediatric populations are more stringent.

Pediatric vaccine candidates' development may require additional studies to determine safe dosing and long-term monitoring. These additional studies may require investment of significant additional resources beyond those required for regulatory approval of the vaccines in adults. Approval of our vaccine candidates may be delayed due to these additional requirements and this may have an adverse effect on the commercial prospects of our vaccine candidates, especially our pediatric vaccine candidate, BWV-201, as well as delay our ability to generate product revenue, possibly materially. In addition, as a result of COVID-19 (or other potential pandemics), there may be a smaller pool of children from which we can enroll for our clinical trials. We cannot guarantee that we will receive regulatory approval to commercialize our product candidates in the pediatric populations or the adult population.

Even if we are able to commercialize our product candidates, such products may become subject to unfavorable pricing regulations, third-party reimbursement practices or healthcare reform initiatives, which would harm our business.

The regulations that govern marketing approvals, pricing, coverage and reimbursement for new drugs vary widely from country to country. In the United States, new and future legislation may significantly change the approval requirements in ways that could involve additional costs and cause delays in obtaining approvals. Some countries require approval of the sale price of a drug before it can be marketed. In many countries, the pricing review period begins after marketing or product-licensing approval is granted. In some foreign markets, prescription pharmaceutical pricing remains subject to continuing governmental control even after initial marketing approval is granted. As a result, we might obtain marketing approval for a drug in a particular country but then be subject to price regulations that delay its commercial launch, possibly for lengthy time periods, and negatively impact the revenue we are able to generate from the sale of the drug in that country. Adverse pricing limitations may hinder our ability to commercialize and generate revenue from our product candidates, even if our product candidates obtain marketing approval.

Our ability to commercialize our current and any future product candidates successfully also will depend in part on the extent to which coverage and adequate reimbursement for these products and related treatments will be available from government health programs, private health insurers, integrated delivery networks and other third-party payors. Third-party payors decide which medications they will pay for and establish reimbursement levels. A significant trend in the U.S. healthcare industry and elsewhere is cost containment. Government authorities and third-party payors have attempted to control costs by limiting coverage and the amount of payment for particular

medications. Increasingly, third-party payors are requiring that drug companies provide predetermined discounts from list prices and are challenging the prices charged for medical products. Coverage and reimbursement may not be available for any product that we commercialize and, if reimbursement is available, the level of reimbursement may not be sufficient for commercial success. Coverage and reimbursement may impact the demand for, or the price of, any product candidate for which we obtain marketing approval. If coverage and reimbursement is not available or is available only to limited levels, we may not be able to successfully commercialize any product candidate for which we obtain marketing approval.

There may be significant delays in obtaining coverage and adequate reimbursement for newly approved products, and coverage may be more limited than the purposes for which the product is approved by the FDA or similar regulatory authorities outside the United States. Moreover, eligibility for coverage and reimbursement does not imply that any product will be paid for in all cases or at a rate that covers our costs, including research, development, manufacture, sale and distribution. Interim reimbursement levels for new drugs, if applicable, may also not be sufficient to cover our costs and may not be made permanent. Coverage and reimbursement rates may vary according to the use of the drug and the medical circumstances under which it is used may be based on reimbursement levels already set for lower cost products or procedures or may be incorporated into existing payments for other services. Net prices for drugs may be reduced by mandatory discounts or rebates required by government healthcare programs or private payors and by any future relaxation of laws that presently restrict imports of drugs from countries where they may be sold at lower prices than in the United States. Commercial third-party payors often rely upon Medicare coverage policies and payment limitations in setting their own reimbursement policies. Our inability to promptly obtain coverage and profitable payment rates from both government-funded programs and private payors for any approved products that we develop could have a material adverse effect on our operating results, our ability to raise capital needed to commercialize our approved products and our overall financial condition.

Any product candidate for which we obtain marketing approval could be subject to marketing restrictions or withdrawal from the market and we may be subject to penalties if we fail to comply with regulatory requirements or if we experience unanticipated problems with our products.

Any product candidate for which we obtain marketing approval, along with the manufacturing processes and facilities, post-approval clinical data, labeling, advertising and promotional activities for such product, will be subject to continual requirements of and review by the FDA and other regulatory authorities. These requirements include submissions of promotional materials and safety and other post-marketing information and reports, registration and listing requirements, current Good Manufacturing Practice (“cGMP”) requirements for product facilities, quality assurance and corresponding maintenance of records and documents and requirements regarding the distribution of samples to physicians and related recordkeeping. Even if marketing approval of a product candidate is granted, the approval may be subject to limitations on the indicated uses for which the product may be marketed or to the conditions of approval or contain requirements for costly post-marketing testing and surveillance to monitor the safety or efficacy of the medicine. The FDA closely regulates the post-approval marketing and promotion of drugs to ensure that they are marketed only for the approved indications and in accordance with the provisions of the approved labeling. However, companies may share truthful and not misleading information that is otherwise consistent with the product’s FDA approved labeling. The FDA imposes stringent restrictions on manufacturers’ communications regarding off-label use and if we do not comply with these restrictions, we may be subject to enforcement actions.

In addition, later discovery of previously unknown problems with our products, manufacturers or manufacturing processes and facilities or failure to comply with regulatory requirements, may result in, among other things:

- restrictions on such products, manufacturers or manufacturing processes or facilities;
- restrictions on the labeling, marketing, distribution or use of a product;
- requirements to conduct post-approval clinical trials, other studies or other post-approval commitments;
- warning or untitled letters;
- withdrawal or recall of the products from the market;
- refusal to approve pending applications or supplements to approved applications that we submit;
- fines, restitution or disgorgement of profits or revenue;

- suspension or withdrawal of marketing approvals;
- refusal to permit the import or export of our products;
- product seizure; and
- injunctions or the imposition of civil or criminal penalties.

Failure to obtain regulatory approvals in foreign jurisdictions will prevent us from marketing our products internationally.

We intend to market future products in international markets. In order to market our future products in regions such as the European Economic Area, or EEA, Asia Pacific, or APAC, and many other foreign jurisdictions, we must obtain separate regulatory approvals.

For example, in the EEA, medicinal products can only be commercialized after obtaining a Marketing Authorization, or MA. Before granting the MA, the European Medicines Agency or the competent authorities of the member states of the EEA make an assessment of the risk-benefit balance of the product on the basis of scientific criteria concerning its quality, safety and efficacy. In Japan, the Pharmaceuticals and Medical Devices Agency, or the PMDA, of the Ministry of Health Labour and Welfare, or MHLW, must approve an application under the Pharmaceutical Affairs Act before a new drug product may be marketed in Japan.

We have had limited interactions with foreign regulatory authorities. The approval procedures vary among countries and can involve additional clinical testing, and the time required to obtain approval may differ from that required to obtain FDA approval. Moreover, clinical studies conducted in one country may not be accepted by regulatory authorities in other countries. Approval by the FDA does not ensure approval by regulatory authorities in other countries, and approval by one or more foreign regulatory authorities does not ensure approval by regulatory authorities in other foreign countries or by the FDA. However, a failure or delay in obtaining regulatory approval in one country may have a negative effect on the regulatory process in others. The foreign regulatory approval process may include all of the risks associated with obtaining FDA approval. We may not obtain foreign regulatory approvals on a timely basis, if at all. We may not be able to file for regulatory approvals and even if we file we may not receive necessary approvals to commercialize our products in any market.

If our products do not receive favorable third-party reimbursement, or if new restrictive legislation is adopted, market acceptance of our products may be limited and we may not generate significant revenues.

Our ability to commercialize our products will depend in part on the extent to which appropriate reimbursement levels for the cost of our proposed formulations and products and related treatments are obtained by governmental authorities, private health insurers and other organizations, such as Health Maintenance Organizations, or HMOs. Reimbursement from third parties depends greatly on our ability to present data which demonstrate positive outcomes and reduced utilization of other products or services as well as cost data which show that treatment costs using the new product are equal to or less than what is currently covered for other products. If our products do not receive favorable third-party reimbursement and patients are unwilling or unable to pay for our products out-of-pocket, it could limit our revenues and harm our business.

The continuing efforts of government and insurance companies, health maintenance organizations and other payers of healthcare costs to contain or reduce costs of health care may affect our future revenues and profitability, and the future revenues and profitability of our potential customers, suppliers and collaborative partners and the availability of capital. For example, in certain foreign markets, pricing or profitability of prescription pharmaceuticals is subject to government control. In the United States, recent federal and state government initiatives have been directed at lowering the total cost of health care. In March 2010, President Obama signed into law the Patient Protection and Affordable Care Act, a sweeping law intended to broaden access to health insurance, reduce or constrain the growth of healthcare spending, enhance remedies against fraud and abuse, add new transparency requirements for healthcare and health insurance industries, impose new taxes and fees on the health industry and impose additional health policy reforms. Federal and state legislatures will likely continue to focus on health care reform, controlling the cost of prescription pharmaceuticals and on the reform of the Medicare and

Medicaid systems. While we cannot predict whether any such legislative or regulatory proposals will be adopted, the announcement or adoption of such proposals could materially harm our business, financial condition and results of operations.

Risks Related to our Business and Industry

We may be adversely affected by the ongoing coronavirus pandemic.

The outbreak of the novel coronavirus COVID-19 ("COVID-19") has evolved into a global pandemic. The coronavirus has spread to many regions of the world. The extent to which the coronavirus impacts our business and operating results will depend on future developments that are highly uncertain and cannot be accurately predicted, including new information that may emerge concerning the coronavirus and the actions to contain the coronavirus or treat its impact, among others.

As a result of the continuing spread of COVID-19, our business operations could be delayed or interrupted. Currently, we operate virtually, i.e., our program activities are and will continue to be carried out, on our behalf, by competent contract research organizations (CROs) with expertise in pre-clinical, clinical and/or chemistry and manufacturing areas. Due to COVID-19, our planned project timelines may be delayed due to reduced availability of human resources or critical supplies needed to carry out such plans. Due to shelter-in-place/stay-at-home orders and other government restrictions, our employees conducting research and development or manufacturing activities at external vendor locations across the globe may not be able to access their laboratory or manufacturing space which may result in our core activities being significantly limited or curtailed, possibly for an extended period of time.

Moreover, our clinical trials may be affected by the COVID-19 pandemic. Site initiation, participant recruitment and enrollment, participant dosing, availability and distribution of clinical trial materials, study monitoring and data analysis may be paused or delayed due to changes in hospital or university policies, federal, state or local regulations, prioritization of hospital resources toward pandemic efforts, or other reasons related to the COVID-19 pandemic. If the coronavirus continues to spread, some participants and clinical investigators may not be able to execute clinical trial protocols per the expected timelines. The new mutations of the virus may also make it harder for us to predict the exact impact (if any) on the progression of COVID-19 on our development programs. For example, quarantines or other travel limitations (whether voluntary or required) may impede participant movement, affect sponsor access to study sites, or interrupt healthcare services, and we may be unable to conduct our clinical trials. Further, if the spread of the COVID-19 pandemic continues and our operations are adversely impacted, we risk a delay, default and/or nonperformance under existing agreements which may increase our costs. These cost increases may not be fully recoverable or adequately covered by insurance.

Infections and deaths related to the pandemic may disrupt the United States' healthcare and healthcare regulatory systems. Such disruptions could divert healthcare resources away from, or materially delay FDA review or review by other regulatory agencies and/or approval with respect to, our clinical trials. It is unknown how long these disruptions could continue, were they to occur. Any elongation or de-prioritization of our clinical trials or delay in regulatory review resulting from such disruptions could materially affect the development and study of our product candidates.

The spread of the coronavirus, which has caused a broad impact globally, including restrictions on travel and quarantine policies put into place by businesses and governments, may have a material economic effect on our business. While the potential economic impact brought by and the duration of the pandemic may be difficult to assess or predict, it has already caused, and is likely to result in further, significant disruption of global financial markets, which may reduce our ability to access capital either at all or on favorable terms. In addition, a recession, depression or other sustained adverse market event resulting from the spread of the coronavirus could materially and adversely affect our business and the value of our common stock.

The ultimate impact of the current pandemic, or any other health epidemic, is highly uncertain and subject to change. We do not yet know the full extent of potential delays or impacts on our business, our clinical trials, our research programs, healthcare systems or the global economy as a whole. However, these effects could have a material impact on our operations, and we will continue to monitor the situation closely.

Our reliance on third parties heightens the risks faced by our business.

We rely on suppliers, vendors and partners for certain key aspects of our business, including support for information technology systems and certain human resource functions. We do not control these partners, but we depend on them in ways that may be significant to us. If these parties fail to meet our expectations or fulfill their obligations to us, we may fail to receive the expected benefits. In addition, if any of these third parties fails to comply with applicable laws and regulations in the course of its performance of services for us, there is a risk that we may be held responsible for such violations as well. This risk is particularly serious in emerging markets, where corruption is often prevalent and where many of the third parties on which we rely do not have internal compliance resources comparable to our own. Any such failures by third parties, in emerging markets or elsewhere, could adversely affect our business, reputation, financial condition or results of operations.

We rely on, and intend to continue to rely on third parties to conduct our pre-clinical testing, research and clinical trials, and those third parties may not perform satisfactorily, including failing to meet deadlines for the completion of such trials, research or testing.

We have been relying on third parties for our preclinical studies, and we expect to continue to rely on third parties, such as CROs, contract manufacturers of clinical supplies, clinical data management organizations, medical institutions and clinical investigators, to conduct our clinical trials and to conduct some aspects of our research and pre-clinical testing. These third parties may terminate their engagements with us at any time. If these third parties do not successfully carry out their duties, meet expected deadlines or conduct our studies in accordance with regulatory requirements or our stated protocols, we will not be able to obtain, or may be delayed in obtaining, marketing approvals for our product candidates and will not be able to, or may be delayed in our efforts to, successfully commercialize our product candidates. Furthermore, these third parties may also have relationships with other entities, some of which may be our competitors. If we are required to enter into alternative arrangements, it could delay our product development activities.

Our reliance on third parties for research and development activities will reduce our control over these activities but will not relieve us of our responsibilities. For example, we will remain responsible for ensuring that each of our clinical trials is conducted in accordance with the general investigational plan and protocols for the trial. Moreover, the FDA and other international regulatory authorities require us to comply with GCP standards for conducting, recording and reporting the results of clinical trials to assure that data and reported results are credible and accurate and that the rights, integrity and confidentiality of trial participants are protected. We also are required to register ongoing clinical trials and post the results of completed clinical trials on a government-sponsored database, available at *www.clinicaltrials.gov*, within certain timeframes. Failure to do so can result in fines, adverse publicity and civil and criminal sanctions.

Upon commercialization of our products, we may be dependent on third parties to market, distribute and sell our products.

Our ability to receive revenues may be dependent upon the sales and marketing efforts of any future co-marketing partners and third-party distributors. At this time, we have not entered into an agreement with any commercialization partner and only plan to do so prior to commercialization. If we fail to reach an agreement with any commercialization partner, or upon reaching such an agreement that partner fails to sell a large volume of our products, it may have a negative impact on our business, financial condition and results of operations.

We have no experience manufacturing product candidates on a clinical or commercial scale and will be dependent on third parties for the manufacture of our product candidates. If we experience problems with any of these third parties, they could delay clinical development or marketing approval of our product candidates or our ability to sell any approved products.

We do not have any manufacturing facilities. We expect to rely on third-party manufacturers for the manufacture of our product candidates for clinical trials and for commercial supply of any product candidate for which we obtain marketing approval.

We may be unable to establish agreements with third-party manufacturers for clinical or commercial supply on terms favorable to us, or at all. Even if we are able to establish agreements with third-party manufacturers, reliance on third-party manufacturers entails additional risks, including:

- reliance on the third party for regulatory compliance and quality assurance;
- the possible breach of the manufacturing agreement by the third party, including the inability to supply sufficient quantities or to meet quality standards or timelines; and
- the possible termination or nonrenewal of the agreement by the third party at a time that is costly or inconvenient for us.

Third-party manufacturers may not be able to comply with U.S. cGMPs or similar regulatory requirements outside the United States. Our failure, or the failure of our third-party manufacturers, to comply with cGMPs or other applicable regulations, even if such failures do not relate specifically to our product candidates or approved products, could result in sanctions being imposed on us or the manufacturers, including fines, injunctions, civil penalties, delays, suspension or withdrawal of approvals, license revocation, seizures or recalls of product candidates, operating restrictions and criminal prosecutions, any of which could adversely affect supplies of our product candidates and harm our business and results of operations.

Any product that we develop may compete with other product candidates and products for access to these manufacturing facilities. There are a limited number of manufacturers that operate under cGMPs and that might be capable of manufacturing for us.

Any performance failure on the part of our manufacturers, including a failure that may not relate specifically to our product candidates or approved products, could delay clinical development or marketing approval or adversely impact our ability to generate commercial sales. If our contract manufacturers cannot perform as agreed, we may be required to replace that manufacturer.

Our anticipated future dependence upon others for the manufacture of our current and future product candidates or products may adversely affect our future profit margins and our ability to commercialize any product candidates that receive marketing approval on a timely and competitive basis.

Furthermore, we expect to rely on third parties to release, label, store and distribute drug supplies for our clinical trials. Any performance failure on the part of these third parties, including a failure that may not relate specifically to our product candidates, could delay or otherwise adversely impact clinical development or marketing approval of our product candidates or commercialization of our drug, producing losses and depriving us of potential revenue.

Moreover, our manufacturers and suppliers may experience difficulties related to their overall businesses and financial stability, which could result in delays or interruptions of supply of our product candidates.

Manufacturing risks may adversely affect our ability to manufacture our product and could reduce our gross margin and profitability.

Our business strategy depends on our ability to manufacture our product candidates s in sufficient quantities and on a timely basis so as to meet our obligations with respect to our clinical trials and upon marketing approval, to meet consumer demand, while adhering to product quality standards, complying with regulatory requirements and managing manufacturing costs. We are subject to numerous risks relating to our manufacturing capabilities, including:

- quality or reliability defects in product components that we source from third-party suppliers, including manufacturing compliance with federal and state regulations;
- our inability to secure product components in a timely manner, in sufficient quantities or on commercially reasonable terms;
- our failure to increase production of products to meet demand
- our inability to modify production lines to enable us to efficiently produce future products or implement changes in current products in response to regulatory requirements; and
- Potential damage to or destruction of our manufacturing equipment or manufacturing facility.

If demand for our product candidates increases in the future, we will have to invest additional resources to purchase components, hire and train employees, and enhance our manufacturing processes. If we fail to increase our production capacity efficiently, our sales may not increase in line with our forecasts and our operating margins could fluctuate or decline. In addition, although we expect some of our product candidates in development to share product features and components, manufacturing of some of our product candidates may require the modification of our production lines, the hiring of specialized employees, the identification of new suppliers for specific components, or the development of new manufacturing technologies. It may not be possible for us to manufacture these product candidates at a cost or in quantities sufficient to make these product candidates commercially viable. Any of these factors may affect our ability to manufacture our product and could reduce our gross margin and profitability.

We maintain single supply relationships for certain key components, and our business and operating results could be harmed if supply is restricted or ends or the price of raw materials used in its manufacturing process increases.

We are dependent on sole suppliers or a limited number of suppliers for certain components that are integral to its finished products. If these or other suppliers encounter financial, operating or other difficulties or if our relationship with them changes, we may be unable to quickly establish or qualify replacement sources of supply and could face production interruptions, delays and inefficiencies. In addition, technology changes by our vendors could disrupt access to required manufacturing capacity or require expensive, time consuming development efforts to adapt and integrate new equipment or processes. Our growth may exceed the capacity of one or more of these suppliers to produce the needed equipment and materials in sufficient quantities to support our growth. Any one of these factors could harm our business and growth prospects.

We may not be able to manage our manufacturing and supply chain effectively, which would harm our results of operations.

We must accurately forecast our clinical trial obligations, and, in the future, market demand, for our product candidates in order to have adequate product inventory available to fulfil our timeline and customer orders timely. Our forecasts will be based on multiple assumptions that may cause our estimates to be inaccurate, and thus affect our ability to ensure adequate manufacturing capability to satisfy product candidate needs or market demand. Any material delay in our ability to obtain timely product inventories from our manufacturing facility and our ingredient suppliers could prevent us from satisfying increased consumer demand for our products, resulting in material harm to our clinical trials, brand and business. In addition, we will need to continuously monitor our inventory and product mix against forecasted demand to avoid having inadequate product inventory or having too much product inventory on hand. If we are unable to manage our supply chain effectively, our operating costs may increase materially.

We may in the future have conflicts with our current or future partners or third party providers that could delay or prevent the development or commercialization of our current and future product candidates.

We may in the future have conflicts with our current or future partners or third party providers, such as conflicts concerning the interpretation of pre-clinical or clinical data, the achievement of milestones, the interpretation of contractual obligations, payments for services, development obligations or the ownership of intellectual property developed during our collaboration. If any conflicts arise with any of our partners, such partner may act in a manner that is adverse to our best interests. Any such disagreement could result in one or more of the following, each of which could delay or prevent the development or commercialization of our current and future product candidates, and in turn prevent us from generating revenues:

- unwillingness on the part of a partner to pay us milestone payments or royalties we believe are due to us under a collaboration;
- uncertainty regarding ownership of intellectual property rights arising from our collaborative activities, which could prevent us from entering into additional collaborations;
- unwillingness by the partner to cooperate in the development or manufacture of the product, including providing us with product data or materials;
- unwillingness on the part of a partner to keep us informed regarding the progress of its development and commercialization activities or to permit public disclosure of the results of those activities;

- initiating of litigation or alternative dispute resolution options by either party to resolve the dispute; or
- attempts by either party to terminate the agreement.

Our product candidates may face competition sooner than anticipated from biosimilar products.

Even if we are successful in achieving regulatory approval to commercialize a product candidate faster than our competitors, our product candidates may face competition from biosimilar products. In the United States, our product candidates are regulated by the FDA as biologic products and we intend to seek approval for these product candidates pursuant to the BLA pathway. The Biologics Price Competition and Innovation Act of 2009, or BPCIA, created an abbreviated pathway for the approval of biosimilar and interchangeable biologic products. The abbreviated regulatory pathway establishes legal authority for the FDA to review and approve biosimilar biologics, including the possible designation of a biosimilar as "interchangeable" based on its similarity to an existing brand product. Under the BPCIA, an application for a biosimilar product cannot be approved by the FDA until 12 years after the original branded product was approved under a BLA. The law is complex and is still being interpreted and implemented by the FDA. As a result, its ultimate impact, implementation, and meaning are subject to uncertainty.

There is a risk that any exclusivity we may be afforded if any of our product candidates are approved as a biologic product under a BLA could be shortened due to congressional action, the results of recent litigation, or otherwise, or that the FDA will not consider our product candidates to be reference products for competing products, potentially creating the opportunity for generic or biosimilar competition sooner than anticipated. Moreover, the extent to which a biosimilar product, once approved, will be substituted for any one of our reference products in a way that is similar to traditional generic substitution for non-biologic products is not yet clear, and will depend on a number of marketplace and regulatory factors that are still developing. In addition, a competitor could decide to forego the biosimilar approval path and submit a full BLA after completing its own preclinical studies and clinical trials. In such cases, any exclusivity to which we may be eligible under the BPCIA would not prevent the competitor from marketing its product as soon as it is approved.

In addition, critics of the 12-year exclusivity period in the biosimilar pathway law will likely continue to seek to shorten the data exclusivity period and/or to encourage the FDA to interpret narrowly the law's provisions regarding which new products receive data exclusivity. In December 2019, the US agreed to remove from the United States-Mexico-Canada Agreement a requirement for at least 10 years of data exclusivity for biologic products. Also, the FDA is considering whether subsequent changes to a licensed biologic would be protected by the remainder of the reference product's original 12-year exclusivity period (a concept known in the generic drug context as "umbrella exclusivity"). If the FDA were to decide that umbrella exclusivity does not apply to biological reference products or were to make other changes to the exclusivity period, this could expose us to biosimilar competition at an earlier time. There also have been, and may continue to be, legislative and regulatory efforts to promote competition through policies enabling easier generic and biosimilar approval and commercialization, including efforts to lower standards for demonstrating biosimilarity or interchangeability, limit patents that may be litigated and/or patent settlements and implement preferential reimbursement policies for biosimilars.

If competitors are able to obtain marketing approval for biosimilars referencing our product candidates, if approved, such products may become subject to competition from such biosimilars, with the attendant competitive pressure and potential adverse consequences. Such competitive products may be able to immediately compete with us in each indication for which our product candidates may have received approval.

Our primary competitors have significantly greater resources and experience than we do, which may make it difficult for us to successfully develop our vaccine candidates, or may result in others discovering, developing or commercializing products before or more successfully than us.

The vaccine market is intensely competitive and is dominated by a small number of multinational, globally established pharmaceutical corporations with significant resources; Pfizer, Merck, GlaxoSmithKline and Sanofi together control approximately 75% of the global vaccine market. We may also face competition from many different sources, including pharmaceutical and biotechnology companies, academic institutions, governmental agencies and public and private research institutions. For example, Sanofi and SK Chemicals have partnered to develop a PCV, and Affinivax and Astellas have partnered to develop an affinity-bound pneumococcal vaccine.

Vaccine candidates that we successfully develop and commercialize may compete with existing vaccines and new vaccines that may become available in the future. Many of our competitors have substantially greater financial, lobbying, technical, human and other resources than we do and may be better equipped to develop, manufacture and market technologically superior vaccines, including the potential that our competitors may develop chemical processes or utilize novel technologies for developing vaccines that may be superior to those we employ. In addition, many of these competitors have significantly greater experience than we have in undertaking preclinical testing and clinical trials of new products and in obtaining regulatory approvals, including for many vaccine franchises. Accordingly, our competitors may succeed in obtaining FDA approval or a preferred recommendation for their products. For example, Prevnar 13 obtained FDA approval for the prevention of invasive pneumococcal disease, or IPD, in infants based on non-inferior IgG antibody responses relative to Prevnar, using the surrogate immune endpoints established by the prior Prevnar field efficacy study. Pfizer is currently implementing a similar approach to development of its 20-valent PCV vaccine candidate, and may have a more efficient path to regulatory approval given Pfizer's and the FDA's previous experience with Prevnar 13.

Many of our competitors have established distribution channels for the commercialization of their vaccine products, whereas we have no such established channels or capabilities. In addition, many competitors have greater name recognition, more extensive collaborative relationships or the ability to leverage a broader vaccine portfolio. Our commercial opportunity could be reduced or eliminated if our competitors develop and commercialize vaccines that are safer, more effective, more convenient, less expensive or with a more favorable label than any vaccine candidates that we may develop.

As a result of these factors, our competitors may obtain regulatory approval of their products before we are able to, which may limit our ability to develop or commercialize our vaccine candidates. Our competitors may also develop vaccines that are safer, more effective, more widely accepted or less expensive than ours, and may also be more successful than we are in manufacturing and marketing their products. These advantages could render our vaccine candidates obsolete or non-competitive before we can recover the costs of such vaccine candidates' development and commercialization.

Mergers and acquisitions in the pharmaceutical and biotechnology industries may result in even more resources being concentrated among a smaller number of our competitors. Smaller and early-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies. These third parties compete with us in recruiting and retaining qualified scientific, management and commercial personnel, establishing clinical trial sites and subject enrollment for clinical trials, as well as in acquiring technologies complementary to, or necessary for, our programs.

Product liability lawsuits against us could cause us to incur substantial liabilities and to limit commercialization of any products that we may develop.

We face an inherent risk of product liability exposure related to the testing of our current product candidates or future product candidates in human clinical trials and will face an even greater risk if we commercially sell any products that we may develop. Product liability claims may be brought against us by subjects enrolled in our clinical trials, patients, healthcare providers or others using, administering or selling our product. If we cannot successfully defend ourselves against claims that our product candidates or product caused injuries, we could incur substantial liabilities. Regardless of merit or eventual outcome, liability claims may result in:

- decreased demand for any product candidates or products that we may develop;
- termination of clinical trial sites or entire clinical trial programs;
- injury to our reputation and significant negative media attention;
- withdrawal of clinical trial participants;
- significant costs to defend the related litigation;
- substantial monetary awards to trial subjects or patients;
- loss of revenue;

- diversion of management and scientific resources from our business operations; and
- the inability to commercialize any products that we may develop.

Prior to engaging in future clinical trials, we intend to obtain product liability insurance coverage at a level that we believe is customary for similarly situated companies and adequate to provide us with insurance coverage for foreseeable risks; however, we may be unable to obtain such coverage at a reasonable cost, if at all. If we are able to obtain product liability insurance, we may not be able to maintain insurance coverage at a reasonable cost or in an amount adequate to satisfy any liability that may arise and such insurance may not be adequate to cover all liabilities that we may incur. Furthermore, we intend to expand our insurance coverage for products to include the sale of commercial products if we obtain regulatory approval for our product candidates in development, but we may be unable to obtain commercially reasonable product liability insurance for any products that receive regulatory approval. Large judgments have been awarded in class action lawsuits based on drugs that had unanticipated side effects. A successful product liability claim or series of claims brought against us, particularly if judgments exceed our insurance coverage, could decrease our cash and adversely affect our business.

We may engage in acquisitions that could disrupt our business, cause dilution to our stockholders or reduce our financial resources.

In the future, we may enter into transactions to acquire other businesses, products or technologies. If we do identify suitable candidates, we may not be able to make such acquisitions on favorable terms, or at all. Any acquisitions we make may fail to strengthen our competitive position and these transactions may be viewed negatively by customers or investors. We may decide to incur debt in connection with an acquisition or issue our common stock or other equity securities to the stockholders of the acquired company, which would reduce the percentage ownership of our existing stockholders. We could incur losses resulting from undiscovered liabilities of the acquired business that are not covered by the indemnification we may obtain from the seller. In addition, we may not be able to successfully integrate the acquired personnel, technologies and operations into our existing business in an effective, timely and non-disruptive manner. Acquisitions may also divert management attention from day-to-day responsibilities, increase our expenses and reduce our cash available for operations and other uses. We cannot predict the number, timing or size of future acquisitions or the effect that any such transactions might have on our operating results.

Security threats to our information technology infrastructure and/or our physical buildings could expose us to liability and damage our reputation and business.

It is essential to our business strategy that our technology and network infrastructure and our physical buildings remain secure and are perceived by our customers and corporate partners to be secure. Despite security measures, however, any network infrastructure may be vulnerable to cyber-attacks by hackers and other security threats. We may face cyber-attacks that attempt to penetrate our network security, sabotage or otherwise disable our research, products and services, misappropriate our or our customers' and partners' proprietary information, which may include personally identifiable information, or cause interruptions of our internal systems and services. Despite security measures, we also cannot guarantee security of our physical buildings. Physical building penetration or any cyber-attacks could negatively affect our reputation, damage our network infrastructure and our ability to deploy our products and services, harm our relationship with customers and partners that are affected, and expose us to financial liability.

Additionally, there are a number of state, federal and international laws protecting the privacy and security of health information and personal data. For example, the Health Insurance Portability and Accountability Act of 1996, or HIPAA, imposes limitations on the use and disclosure of an individual's healthcare information by healthcare providers, healthcare clearinghouses, and health insurance plans, or, collectively, covered entities, and also grants individuals rights with respect to their health information. HIPAA also imposes compliance obligations and corresponding penalties for non-compliance on individuals and entities that provide services to healthcare providers and other covered entities. As part of the American Recovery and Reinvestment Act of 2009, or ARRA, the privacy and security provisions of HIPAA were amended. ARRA also made significant increases in the penalties for improper use or disclosure of an individual's health information under HIPAA and extended enforcement authority to state attorneys general. As amended by ARRA and subsequently by the final omnibus rule adopted in 2013, HIPAA also imposes notification requirements on covered entities in the event that certain health information has been

inappropriately accessed or disclosed, notification requirements to individuals, federal regulators, and in some cases, notification to local and national media. Notification is not required under HIPAA if the health information that is improperly used or disclosed is deemed secured in accordance with encryption or other standards developed by the U.S. Department of Health and Human Services. Most states have laws requiring notification of affected individuals and/or state regulators in the event of a breach of personal information, which is a broader class of information than the health information protected by HIPAA. Many state laws impose significant data security requirements, such as encryption or mandatory contractual terms, to ensure ongoing protection of personal information. Activities outside of the U.S. implicate local and national data protection standards, impose additional compliance requirements and generate additional risks of enforcement for non-compliance. We may be required to expend significant capital and other resources to ensure ongoing compliance with applicable privacy and data security laws, to protect against security breaches and hackers or to alleviate problems caused by such breaches.

We will need to grow the size of our organization in the future, and we may experience difficulties in managing this growth.

As of September 30, 2021, we had 2 full-time and 7 subcontracted employees. We will need to grow the size of our organization in order to support our continued development and potential commercialization of our product candidates. As our development and commercialization plans and strategies continue to develop, our need for additional managerial, operational, manufacturing, sales, marketing, financial and other resources may increase. Our management, personnel and systems currently in place may not be adequate to support this future growth. Future growth would impose significant added responsibilities on members of management, including:

- managing our clinical trials effectively;
- identifying, recruiting, maintaining, motivating and integrating additional employees;
- managing our internal development efforts effectively while complying with our contractual obligations to licensors, licensees, contractors and other third parties;
- improving our managerial, development, operational, information technology, and finance systems; and
- expanding our facilities.

If our operations expand, we will also need to manage additional relationships with various strategic partners, suppliers and other third parties. Our future financial performance and our ability to commercialize our product candidates and to compete effectively will depend, in part, on our ability to manage any future growth effectively, as well as our ability to develop a sales and marketing force when appropriate. To that end, we must be able to manage our development efforts and pre-clinical studies and clinical trials effectively and hire, train and integrate additional management, research and development, manufacturing, administrative and sales and marketing personnel. The failure to accomplish any of these tasks could prevent us from successfully growing our company.

Our future success depends on our ability to retain our executive officers and to attract, retain and motivate qualified personnel.

We are highly dependent upon our personnel, including Joseph Hernandez, our Chief Executive Officer and members of our board of directors. The loss of Mr. Hernandez's services could impede the achievement of our research, development and commercialization objectives. We have not obtained, do not own, nor are we the beneficiary of, key-person life insurance. Our future growth and success depend on our ability to recruit, retain, manage and motivate our employees. The loss of any member of our senior management team or the inability to hire or retain experienced management personnel could compromise our ability to execute our business plan and harm our operating results. Because of the specialized scientific and managerial nature of our business, we rely heavily on our ability to attract and retain qualified scientific, technical and managerial personnel. The competition for qualified personnel in the biotechnology field is intense and as a result, we may be unable to continue to attract and retain qualified personnel necessary for the development of our business.

Our Chief Executive Officer, Joseph Hernandez, and our Chief Financial Officer, Jon Garfield, also hold certain management positions and directorships of other companies and may allocate their time to such other businesses, thereby causing conflicts of interest in their determination as to how much time to devote to our affairs. This could have a negative impact on our ability to implement our plan of operation.

Our Chief Executive Officer, Joseph Hernandez is engaged in other business endeavors for which he may be entitled to substantial compensation, which may result in a conflict of interest in allocating his time between our operations and his other businesses. Pursuant to Mr. Hernandez's employment agreement that will be effective as of the consummation of this offering, Mr. Hernandez shall be employed with the Company on a full-time basis, but shall be permitted to participate in certain limited business activities. Subject to our Board's prior approval, Mr. Hernandez may serve as an officer, stakeholder, or member of the board of directors or advisory board (or the equivalent in the case of a non-corporate entity) of non-competing for-profit businesses and charitable organizations, provided, however, that such activities do not materially interfere, individually or in the aggregate, with the performance of his duties and responsibilities to Blue Water Vaccines. Accordingly, although Mr. Hernandez's primary occupation is his service to Blue Water Vaccines, he also holds certain management positions and directorships of other companies, and may allocate his time to such other businesses, thereby causing conflicts of interest in his determination as to how much time to devote to our affairs.

Additionally, our Chief Financial Officer following the offering, Jon Garfield, is engaged in other business endeavors for which he may be entitled to substantial compensation, which may result in a conflict of interest in allocating his time between our operations and his other businesses. Pursuant to Mr. Garfield's employment agreement that will be effective as of the consummation of this offering, Mr. Garfield shall be employed with the Company on a full-time basis, but shall be permitted to participate in certain limited business activities, subject to the restrictions imposed on Mr. Hernandez as described above. Accordingly, Mr. Garfield holds certain management positions and directorships of other companies, and may allocate his time to such other businesses, thereby causing conflicts of interest in his determination as to how much time to devote to our affairs

Each of Messrs. Hernandez and Garfield may also have competitive fiduciary obligations and pecuniary interests relating to their other business ventures that conflict with our interests. Each of Messrs. Hernandez and Garfield's employment agreement contains certain restrictive covenants while they are employed at Blue Water Vaccines. These restrictive covenants, generally, restrict Messrs. Hernandez and Garfield from engaging in any other business or occupation that (x) conflicts with the interests of the Company, (y) interferes with the proper and efficient performance of his duties for the Company, or (z) interferes with his exercise of judgment in the Company's best interests. Messrs. Hernandez and Garfield are further subject to general restrictions regarding the solicitation of employees, certain customers, as well as the use or disclosure of any confidential information, of the business of Blue Water Vaccines. Notwithstanding the foregoing, to the extent that these additional activities may have a conflict between their interests and ours, this could have a negative impact on our ability to implement our plan of operations.

Certain significant personnel may allocate their time to other businesses, which may cause conflicts of interest in their determination as to how much time to devote to our affairs and potentially competitive fiduciary and pecuniary interests that conflict with our interests.

Our executive officers are supported by Ronald Cobb, Brian Price and Andrew Skibo, who provide valuable technical and strategic capabilities to us. They are not currently required to commit their full time to our affairs. As such, they may allocate their time to other businesses. From time to time, those other commitments may limit the nature of services that Messrs. Cobb, Price and Skibo provide to our Company, for instance, where such activities may involve overlapping industries and products. If these individuals' other business affairs require them to devote substantial amounts of time to such affairs in excess of their current commitment levels, it could limit their ability to devote time or resources to our affairs, which may have a negative impact on our ability to complete our plan of operations.

Inadequate funding for the FDA, the SEC and other government agencies could hinder their ability to hire and retain key leadership and other personnel, prevent new products and services from being developed or commercialized in a timely manner or otherwise prevent those agencies from performing normal business functions on which the operation of our business may rely, which could negatively impact our business.

The ability of the FDA to review and approve new products can be affected by a variety of factors, including government budget and funding levels, ability to hire and retain key personnel and accept the payment of user fees, and statutory, regulatory, and policy changes. Average review times at the agency have fluctuated in recent years as a result. In addition, government funding of the SEC and other government agencies on which our operations may rely, including those that fund research and development activities is subject to the political process, which is inherently fluid and unpredictable.

Disruptions at the FDA and other agencies may also slow the time necessary for new drugs to be reviewed and/or approved by necessary government agencies, which would adversely affect our business. For example, over the last several years, including beginning on December 22, 2018, the U.S. government has shut down several times and certain regulatory agencies, such as the FDA and the SEC, have had to furlough critical FDA, SEC and other government employees and stop critical activities. If a prolonged government shutdown occurs, it could significantly impact the ability of the FDA to timely review and process our regulatory submissions, which could have a material adverse effect on our business. Further, upon completion of this offering and in our operations as a public company, future government shutdowns could impact our ability to access the public markets and obtain necessary capital in order to properly capitalize and continue our operations.

We may be adversely affected by natural disasters, pandemics and other catastrophic events, and by man-made problems such as terrorism, that could disrupt our business operations and our business continuity and disaster recovery plans may not adequately protect us from a serious disaster.

If a disaster, power outage or other event occurred that prevented us from using all or a significant portion of our headquarters, that damaged critical infrastructure, such as enterprise financial systems, manufacturing resource planning or enterprise quality systems, or that otherwise disrupted operations, it may be difficult or, in certain cases, impossible for us to continue our business for a substantial period of time. Our contract manufacturers' and suppliers' facilities are located in multiple locations, where other natural disasters or similar events, such as blizzards, tornadoes, fires, explosions or large-scale accidents or power outages, and other public health emergencies could severely disrupt our operations and have a material adverse effect on our business, financial condition, operating results and prospects. For example, the recent COVID-19 pandemic may cause significant disruption to our business operations, the operations of our third-party contractors and suppliers and the operations of our clinical trials, including as a result of significant restrictions or bans on travel into and within the geographic areas in which our manufacturers product our product candidates or where we conduct our clinical trials. A public health emergency could also affect the operations of the FDA and other regulatory or public health authorities, resulting in delays to meetings related to planned or completed clinical trials and ultimately of reviews and approvals of our product candidates. Such disruption could impede, delay, limit or prevent our employees and third-party contractors from beginning or continuing research and development or clinical trial-related activities, which may impede, delay, limit or prevent initiation or completion of our ongoing clinical trials and preclinical research and ultimately lead to the delay or denial of regulatory approval of our product candidates, which could seriously harm our operations and financial condition.

Our employees, independent contractors, principal investigators, consultants, vendors and clinical research organizations, or CROs, may engage in misconduct or other improper activities, including noncompliance with regulatory standards and requirements.

We are exposed to the risk that our employees, independent contractors, principal investigators, consultants, vendors and CROs may engage in fraudulent or other illegal activity. Misconduct by these persons could include intentional, reckless or negligent conduct or unauthorized activity that violates: laws or regulations, including those laws requiring the reporting of true, complete and accurate information to the FDA or foreign regulatory authorities; manufacturing standards; federal, state and foreign healthcare fraud and abuse laws and data privacy; or laws that require the true, complete and accurate reporting of financial information or data. In particular, sales, marketing and other business arrangements in the healthcare industry are subject to extensive laws intended to prevent fraud, kickbacks, self-dealing and other abusive practices. These laws may restrict or prohibit a wide range of business activities, including research, manufacturing, distribution, pricing, discounting, marketing and promotion, sales

commission, customer incentive programs and other business arrangements. Activities subject to these laws also involve the improper use of information obtained in the course of clinical trials, or illegal misappropriation of drug product, which could result in regulatory sanctions or other actions or lawsuits stemming from a failure to comply with such laws or regulations, and serious harm to our reputation. In addition, federal procurement laws impose substantial penalties for misconduct in connection with government contracts and require certain contractors to maintain a code of business ethics and conduct. If any such actions are instituted against us, we may have to terminate employees or others involved and the impact of such termination can result in our experiencing delays and additional costs associated with replacing the services being provided. If we are not successful in defending ourselves or asserting our rights, those actions could have a significant impact on our business, including the imposition of civil, criminal and administrative penalties, damages, monetary fines, possible exclusion from participation in Medicare, Medicaid and other federal healthcare programs, FDA debarment, contractual damages, reputational harm, diminished profits and future earnings, and curtailment of our operations, any of which could adversely affect our ability to operate our business and our operating results.

Macroeconomic pressures in the markets in which we operate, including, but not limited to, the effect of the COVID-19 pandemic may alter the ways in which we conduct our business operations and manage our financial capacities.

To varying degrees, the ways in which we conduct our business operations and manage our financial capacities are influenced by macroeconomic conditions that affect companies directly involved in or providing services related to the drug and biological product development. For example, real GDP growth, business and investor confidence, the COVID-19 pandemic, inflation, employment levels, oil prices, interest rates, tax rates, availability of consumer and business financing, housing market conditions, foreign currency exchange rate fluctuations, costs for items such as fuel and food and other macroeconomic trends can adversely affect not only our decisions and ability to engage in research and development and clinical trials, but also those of our management, employees, third-party contractors, manufacturers and suppliers, competitors, stockholders and regulatory authorities. In addition, geopolitical issues around the world and how our markets are positioned can also impact the macroeconomic conditions and could have a material adverse impact on our financial results.

Economic uncertainty may adversely affect our access to capital, cost of capital and ability to execute our business plan as scheduled.

Generally, worldwide economic conditions remain uncertain. Access to capital markets is critical to our ability to operate. Traditionally, biotechnology companies have funded their research and development expenditures through raising capital in the equity markets. Declines and uncertainties in these markets in the past have severely restricted raising new capital and have affected companies' ability to continue to expand or fund existing research and development efforts. We require significant capital for research and development for our vaccine candidates and clinical trials. The general economic and capital market conditions, both in the U.S. and worldwide, have been volatile in the past and at times have adversely affected our access to capital and increased the cost of capital. There is no certainty that the capital and credit markets will be available to raise additional capital on favorable terms. If economic conditions become worse, our future cost of equity or debt capital and access to the capital markets could be adversely affected. In addition, if we are unable to access the capital markets on favorable terms, our ability to execute our business plan as scheduled would be compromised. Moreover, we rely and intend to rely on third-parties, including clinical research organizations, contract manufacturing organizations and other important vendors and consultants. Global economic conditions may result in a disruption or delay in the performance of our third-party contractors and suppliers. If such third-parties are unable to adequately satisfy their contractual commitments to us in a timely manner, our business could be adversely affected.

Risks Related to Our Intellectual Property

It is difficult and costly to protect our proprietary rights, and we may not be able to ensure their protection. If our patent position does not adequately protect our product candidates, others could compete against us more directly, which would harm our business, possibly materially.

Our commercial success will depend in part on obtaining and maintaining patent protection and trade secret protection of our current product candidates and future product candidates, the processes used to manufacture them and the methods for using them, as well as successfully defending these patents against third-party challenges.

Our ability to stop third parties from making, using, selling, offering to sell or importing our product candidates is dependent upon the extent to which we have rights under valid and enforceable patents or trade secrets that cover these activities.

The patent positions of biotechnology and pharmaceutical companies can be highly uncertain and involve complex legal and factual questions for which important legal principles remain unresolved. No consistent policy regarding the breadth of claims allowed in pharmaceutical patents has emerged to date in the U.S. or in foreign jurisdictions outside of the U.S. Changes in either the patent laws or interpretations of patent laws in the U.S. and other countries may diminish the value of our intellectual property. Accordingly, we cannot predict the breadth of claims that may be enforced in the patents that may be issued from the applications we currently license or may in the future own or license from third parties. Further, if any patents we obtain or license are deemed invalid and unenforceable, our ability to commercialize or license our product candidates or technology could be adversely affected.

Others may file patent applications covering products and technologies that are similar, identical or competitive to ours or important to our business. We cannot be certain that any patent application owned by a third party will not have priority over patent applications filed or in-licensed by us, or that we or our licensors will not be involved in interference, opposition, re-examination, review, reissue, post grant review or invalidity proceedings before U.S. or non-U.S. patent offices. Such proceedings are also expensive and time consuming.

The degree of future protection for our proprietary rights is uncertain because legal means afford only limited protection and may not adequately protect our rights or permit us to gain or keep our competitive advantage. For example:

- others may be able to make compounds that are similar to our product candidates, but that are not covered by the claims of our licensed patents;
- any patents that we obtain from licensing or otherwise may not provide us with any competitive advantages;
- any granted patents that we rely upon may be held invalid or unenforceable as a result of legal challenges by third parties; and
- the patents of others may have an adverse effect on our business.

We are dependent on licensed intellectual property. If we were to lose our rights to licensed intellectual property, we may not be able to continue developing or commercializing our product candidates, if approved. If we breach any of the agreements under which we license the use, development and commercialization rights to our product candidates or technology from third parties or, in certain cases, we fail to meet certain development deadlines, we could lose license rights that are important to our business.

We do not currently own any patents, and we are heavily reliant upon a number of license agreements under which we are granted rights to intellectual property that are important to our business and we may need or choose to enter into additional license agreements in the future. Our existing license agreements impose, and we expect that future license agreements will impose on us, various development, regulatory and/or commercial diligence obligations, payment of milestones and/or royalties and other obligations. If we fail to comply with our obligations under these agreements, or we are subject to a bankruptcy, the licensor may have the right to terminate the license, in which event we would not be able to market products covered by the license. Our business could suffer, for example, if any current or future licenses terminate, if the licensors fail to abide by the terms of the license, if the licensed patents or other rights are found to be invalid or unenforceable, or if we are unable to enter into necessary licenses on acceptable terms.

Licensing of intellectual property is of critical importance to our business and involves complex legal, business and scientific issues. Disputes may arise between us and our licensors regarding intellectual property subject to a license agreement, including:

- the scope of rights granted under the license agreement and other interpretation-related issues;
- whether and the extent to which our technology and processes infringe on intellectual property of the licensor that is not subject to the licensing agreement;

- our right to sublicense patent and other rights to third parties;
- our diligence obligations with respect to the use of the licensed technology in relation to our development and commercialization of our product candidates, and what activities satisfy those diligence obligations;
- our obligation to pursue or license others to pursue development of indications we are not currently pursuing;
- the ownership of inventions and know-how resulting from the joint creation or use of intellectual property by our licensors and us and our partners;
- our right to transfer or assign the license; and
- the effects of termination.

If disputes over intellectual property that we have licensed prevent or impair our ability to maintain our current licensing arrangements on acceptable terms, we may be unable to successfully develop and commercialize the affected product candidates.

We have entered into several licenses to support our various programs. Termination of any of these license agreements would have a material adverse impact on our ability to develop and commercialize derived products under each respective agreement.

We may enter into additional licenses to third-party intellectual property that are necessary or useful to our business. Our current licenses and any future licenses that we may enter into impose various royalty payment, milestone, and other obligations on us. Under some license agreements, we may not control prosecution of the licensed intellectual property, or may not have the first right to enforce the intellectual property. In those cases, we may not be able to adequately influence patent prosecution or enforcement, or prevent inadvertent lapses of coverage due to failure to pay maintenance fees. If we fail to comply with any of our obligations under a current or future license agreement, the licensor may allege that we have breached our license agreement, and may accordingly seek to terminate our license. Termination of any of our current or future licenses could result in our loss of the right to use the licensed intellectual property, which could materially adversely affect our ability to develop and commercialize a product candidate or product, if approved, as well as harm our competitive business position and our business prospects. Under some license agreements, termination may also result in the transfer of or granting in rights under certain of our intellectual property and information related to the product candidate being developed under the license, such as regulatory information.

The agreements under which we license intellectual property or technology to or from third parties are complex, and certain provisions in such agreements may be susceptible to multiple interpretations. The resolution of any contract interpretation disagreement that may arise could narrow what we believe to be the scope of our rights to the relevant intellectual property or technology or increase what we believe to be our financial or other obligations under the relevant agreement, either of which could have a material adverse effect on our business, financial condition, results of operations and prospects. Moreover, if disputes over intellectual property that we have licensed prevent or impair our ability to maintain our current licensing arrangements on commercially acceptable terms, we may be unable to successfully develop and commercialize the affected product candidates

In addition, if our licensors fail to abide by the terms of the license, if the licensors fail to prevent infringement by third parties, if the licensed patents or other rights are found to be invalid or unenforceable, or if we are unable to enter into necessary licenses on acceptable terms, our business could suffer. Moreover, our licensors may own or control intellectual property that has not been licensed to us and, as a result, we may be subject to claims, regardless of their merit, that we are infringing, misappropriating or otherwise violating the licensor's rights.

Similarly, if we are unable to successfully obtain rights to required third-party intellectual property rights or maintain the existing intellectual property rights we have, we may have to seek alternative options, such as developing new product candidates with design-around technologies, which may require more time and investment, or abandon development of the relevant research programs or product candidates and our business, financial condition, results of operations and prospects could suffer.

Some of the intellectual property covered by our licenses concerns patent applications and provisional applications. We cannot assure investors that any of the currently pending or future patent applications will result in granted patents, nor can we predict how long it will take for such patents to be granted.

Some of intellectual property covered by our licenses concerns certain, specified patent rights (including patent applications, provisional patent applications and PCT patent applications). While in some instances, the licensors have agreed to assume responsibility for the preparation, filing, prosecution and maintenance of patent applications covered by the licensed patent rights, we cannot be certain as to when or if final patents will be issued for those patent applications covered by the licensed patent rights. However, the licensors may not successfully prosecute certain patent applications, the prosecution of which they control, under which we are only a licensee and on which our business substantially depends. Even if patents issue from these applications, there is no assurance that the patents will be free from defects or survive validity or enforceability challenges, the licensors may fail to maintain these patents, may decide not to pursue litigation against third-party infringers, may fail to prove infringement or may fail to defend against counterclaims of patent invalidity or unenforceability.

Moreover, it is possible that the licensed pending patent applications will not result in granted patents, and even if such pending patent applications grant as patents, they may not provide a basis for intellectual property protection of commercially viable vaccine products or may not provide us with any competitive advantages. Further, it is possible that, for any of the patents that may be granted in the future, others will design around the licensed patent rights or identify methods for preventing or treating infectious diseases that do not concern the rights covered by our licenses. Further, we cannot assure investors that other parties will not challenge any patents granted to the licensors or that courts or regulatory agencies will hold licensor’s patents to be valid or enforceable. We cannot guarantee investors that, if required to defend the covered patents, we will have the funds to or be successful in defending challenges made against the licensed patents and patent applications. Any successful third-party challenge to the licensed patents could result in the unenforceability or invalidity of such patents, or to such patents being interpreted narrowly or otherwise in a manner adverse to our interests. Our ability to establish or maintain a technological or competitive advantage over our competitors may be diminished because of these uncertainties.

Even if patents are issued based on patent applications to which we have been granted a license, because the patent positions of pharmaceutical and biotechnology products are complex and uncertain, we cannot predict the scope and extent of patent protection for our product candidates.

Any patents that may be issued based on patent applications that we have been granted licenses to will not ensure sufficient protection with respect to our activities for a number of reasons, including without limitation the following:

- any issued patents may not be broad or strong enough to prevent competition from other vaccine products including identical or similar products;
- if patents are not issued or if issued patents expire, there would be no protections against competitors making generic equivalents;
- there may be prior art of which we are not aware that may affect the validity or enforceability of a patent claim;
- there may be other patents existing, now or in the future, in the patent landscape for our product candidates that we seek to commercialize or develop, if any, that will affect our freedom to operate;
- if patents that we have been granted licenses to are challenged, a court could determine that they are not valid or enforceable;
- a court could determine that a competitor’s technology or product does not infringe patents that we have been granted licenses to;
- patents to which we have been granted licenses could irretrievably lapse due to failure to pay fees or otherwise comply with regulations, or could be subject to compulsory licensing; and
- if we encounter delays in our development or clinical trials, the period of time during which we could market our products under patent protection would be reduced.

Obtaining and maintaining patent protection depends on compliance with various procedural, document submission, fee payment and other requirements imposed by governmental patent agencies, and patent protection could be reduced or eliminated for noncompliance with these requirements.

Periodic maintenance fees on any issued patent are due to be paid to the United States Patent and Trademark Office (USPTO) and foreign Intellectual Property Offices in several stages over the term of the patent. Maintenance fees are also due for pending patent applications in some countries. The USPTO and various foreign governmental patent agencies require compliance with a number of procedural, documentary, fee payment and other similar provisions during the patent application process. While an inadvertent lapse can in many cases be cured by payment of a late fee or by other means in accordance with the applicable rules, there are situations in which noncompliance can result in abandonment or lapse of the patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction. Noncompliance events that could result in abandonment or lapse of a patent or patent application include, but are not limited to, failure to respond to office actions within prescribed time limits, non-payment of fees and failure to properly legalize and submit formal documents. In such an event, our competitors might be able to enter the market, which would have a material adverse effect on our business.

The life of patent protection is limited, and third parties could develop and commercialize products and technologies similar or identical to ours and compete directly with us after the patent licensed to us expires, which could materially and adversely affect our ability to commercialize our products and technologies.

The life of a patent and the protection it affords is limited. For example, in the United States, if all maintenance fees are timely paid, the natural expiration of a patent is generally 20 years from its earliest U.S. non-provisional filing date. In Europe, the expiration of an invention patent is 20 years from its filing date. Even if we successfully obtain patent protection for an approved vaccine candidate, it may face competition from biosimilar medications. Manufacturers of biosimilar drugs may challenge the scope, validity or enforceability of the patents underlying our technology in court or before a patent office, and the patent holder may not be successful in enforcing or defending those intellectual property rights and, as a result, we may not be able to develop or market the relevant product candidate exclusively, which would materially adversely affect any potential sales of that product.

Given the amount of time required for the development, testing and regulatory review of new vaccine candidates, patents protecting such vaccine candidates might expire before or shortly after such vaccine candidates are commercialized. As a result, the patents and patent applications licensed to us may not provide us with sufficient rights to exclude others from commercializing products similar or identical to ours. Even if we believe that the patents involved are eligible for certain (and time-limited) patent term extensions, there can be no assurance that the applicable authorities, including the FDA and the USPTO, and any equivalent regulatory authority in other countries, will agree with our assessment of whether such extensions are available, and such authorities may refuse to grant extensions to such patents, or may grant more limited extensions than requested. For example, depending upon the timing, duration and specifics of any FDA marketing approval of any product candidates we may develop, one or more of the U.S. patents licensed to us may be eligible for limited patent term extension under the Drug Price Competition and Patent Term Restoration Action of 1984, or Hatch-Waxman Amendments. The Hatch-Waxman Amendments permit a patent extension term of up to five years as compensation for patent term lost during the FDA regulatory review process. A patent term extension cannot extend the remaining term of a patent beyond a total of 14 years from the date of product approval, only one patent may be extended and only those claims covering the approved drug, a method for using it, or a method for manufacturing it may be extended. However, we may not be granted an extension because of, for example, failing to exercise due diligence during the testing phase or regulatory review process, failing to apply within applicable deadlines, failing to apply prior to expiration of relevant patents, or otherwise failing to satisfy applicable requirements. Moreover, the applicable time period or the scope of patent protection afforded could be less than requested. If we are unable to obtain patent term extension or term of any such extension is less than requested, our competitors may obtain approval of competing products following our patent expiration, and our business could be harmed. Changes in either the patent laws or interpretation of the patent laws in the United States and other countries may diminish the value of our patents or narrow the scope of our patent protection.

The patents and pending patent applications licensed to us for our product candidates are expected to expire on various dates. Upon the expiration, we will not be able to assert such licensed patent rights against potential competitors, which would materially adversely affect our business, financial condition, results of operations and prospects.

We may need to license intellectual property from third parties, and such licenses may not be available or may not be available on commercially reasonable terms or at all.

There may be intellectual property rights existing now, or in the future, relevant to our product candidates that we seek to commercialize or develop, if any, that may affect our ability to commercialize such product candidates. Although the Company is not aware of any such intellectual property rights, a third-party may hold intellectual property rights, including patent rights, that are important or necessary to the development or manufacture of our product candidates. Even if all our main product candidates are covered by patents, it may be necessary for us to use the patented or proprietary technology of third parties to commercialize our product candidates, in which case we would be required to obtain a license from these third parties. Such a license may not be available on commercially reasonable terms, or at all, and we could be forced to accept unfavorable contractual terms. In that event, we may be required to expend significant time and resources to redesign our technology, product candidates, or the methods for manufacturing them or to develop or license replacement technology, all of which may not be feasible on a technical or commercial basis. If we are unable to do so, our business could be harmed.

The licensing or acquisition of third-party intellectual property rights is a competitive area, and several more established companies may pursue strategies to license or acquire third party intellectual property rights that we may consider attractive or necessary. These established companies may have a competitive advantage over us due to their size, capital resources and greater clinical development and commercialization capabilities. In addition, companies that perceive us to be a competitor may be unwilling to assign or license rights to us. We also may be unable to license or acquire third party intellectual property rights on terms that would allow us to make an appropriate return on our investment or at all. If we are unable to successfully obtain rights to required third party intellectual property rights or maintain the existing intellectual property rights we have, we may have to abandon development of the relevant program or product candidate, which could have a material adverse effect on our business, financial condition, results of operations, and prospects.

We may infringe the intellectual property rights of others, which may prevent or delay our product development efforts and stop us from commercializing or increase the costs of commercializing our product candidates.

Our success will depend in part on our ability to operate without infringing the proprietary rights of third parties. We are not aware of any third party proprietary rights that our planned products will infringe or misappropriate, but we have not conducted any freedom to operate study as we are in the earliest stages of development. We thus cannot guarantee that our product candidates, or manufacture or use of our product candidates, will not infringe third-party patents. Furthermore, a third party may claim that we are using inventions covered by the third party's patent rights and may go to court to stop us from engaging in our normal operations and activities, including making or selling our product candidates. These lawsuits are costly and could affect our results of operations and divert the attention of managerial and scientific personnel. Some of these third parties may be better capitalized and have more resources than us. There is a risk that a court would decide that we are infringing the third party's patents and would order us to stop the activities covered by the patents. In that event, we may not have a viable way around the patent and may need to halt commercialization of our product candidates. In addition, there is a risk that a court will order us to pay the other party damages for having violated the other party's patents. In addition, we may be obligated to indemnify our licensors and collaborators against certain intellectual property infringement claims brought by third parties, which could require us to expend additional resources. The pharmaceutical and biotechnology industries have produced a proliferation of patents, and it is not always clear to industry participants, including us, which patents cover various types of products or methods of use. The coverage of patents is subject to interpretation by the courts, and the interpretation is not always uniform.

If we are sued for patent infringement, we would need to demonstrate that our product candidates or methods either do not infringe the patent claims of the relevant patent or that the patent claims are invalid, and we may not be able to do this. Proving invalidity is difficult. For example, in the U.S., proving invalidity requires a showing of clear and convincing evidence to overcome the presumption of validity enjoyed by issued patents. Even if we are successful in these proceedings, we may incur substantial costs and diversion of management's time and attention in pursuing these proceedings, which could have a material adverse effect on us. If we are unable to avoid infringing the patent rights of others, we may be required to seek a license, which may not be available, defend an infringement action or challenge the validity of the patents in court. Patent litigation is costly and time consuming. We may not have sufficient resources to bring these actions to a successful conclusion. In addition, if we do not obtain a license,

develop or obtain non-infringing technology, fail to defend an infringement action successfully or have infringed patents declared invalid, we may incur substantial monetary damages, encounter significant delays in bringing our product candidates to market and be precluded from manufacturing or selling our product candidates.

Some of our competitors may be able to sustain the costs of complex patent litigation more effectively than us or the third parties from whom we license intellectual property because they have substantially greater resources. In addition, any uncertainties resulting from the initiation and continuation of any litigation could have a material adverse effect on our ability to raise the funds necessary to continue our operations.

We may become involved in lawsuits to protect or enforce our intellectual property, which could be expensive, time consuming and unsuccessful.

In addition to the possibility of litigation relating to infringement claims asserted against it, we may become a party to other patent litigation and other proceedings, including *inter partes* review proceedings, post-grant review proceedings, derivation proceedings declared by the USPTO and similar proceedings in foreign countries, regarding intellectual property rights with respect to our current or future technologies or product candidates or products. The cost to us of any patent litigation or other proceeding, even if resolved in our favor, could be substantial. Some of our competitors may be able to sustain the costs of such litigation or proceedings more effectively than we can because of their substantially greater financial resources. Patent litigation and other proceedings may also absorb significant management time. Uncertainties resulting from the initiation and continuation of patent litigation or other proceedings could impair our ability to compete in the marketplace.

Competitors may infringe or otherwise violate our intellectual property, including patents that may issue to or be licensed by us. As a result, we may be required to file claims in an effort to stop third-party infringement or unauthorized use. Any such claims could provoke these parties to assert counterclaims against us, including claims alleging that we infringe their patents or other intellectual property rights, and/or that any of our intellectual property, including licensed intellectual property, is invalid and/or unenforceable. This can be prohibitively expensive, particularly for a company of our size, and time-consuming, and even if we are successful, any award of monetary damages or other remedy we may receive may not be commercially valuable. In addition, in an infringement proceeding, a court may decide that our asserted intellectual property is not valid or is unenforceable, or may refuse to stop the other party from using the technology at issue on the grounds that our intellectual property does not cover its technology. An adverse determination in any litigation or defense proceedings could put our intellectual property at risk of being invalidated or interpreted narrowly and could put our patent applications at risk of not issuing.

If the breadth or strength of our patent or other intellectual property rights is compromised or threatened, it could allow third parties to exploit and, in particular, commercialize our technology or products or result in our inability to exploit and/or commercialize our technology and products without infringing third-party intellectual property rights. Further, third parties may be dissuaded from collaborating with us.

Interference or derivation proceedings brought by the USPTO or its foreign counterparts may be necessary to determine the priority of inventions with respect to our patent applications, and we may also become involved in other proceedings, such as re-examination proceedings, before the USPTO or its foreign counterparts. Due to the substantial competition in the pharmaceutical space, the number of such proceedings may increase. This could delay the prosecution of our pending patent applications or impact the validity and enforceability of any future patents that we may obtain. In addition, any such litigation, submission or proceeding may be resolved adversely to us and, even if successful, may result in substantial costs and distraction to our management.

If we are not able to adequately prevent disclosure of trade secrets and other proprietary information, the value of our technology and product could be significantly diminished.

We also rely on trade secrets to protect our proprietary technologies, especially where we do not believe patent protection is appropriate or obtainable. However, trade secrets are difficult to protect. We rely in part on confidentiality agreements with our employees, consultants, outside scientific collaborators, sponsored researchers and other advisors to protect our trade secrets and other proprietary information. These agreements may not effectively prevent disclosure of confidential information and may not provide an adequate remedy in the event of unauthorized disclosure of confidential information. In addition, others may independently discover our trade secrets and proprietary information. For example, the FDA, as part of its transparency initiative, is currently considering whether to make additional information publicly available on a routine basis, including information that we may

consider to be trade secrets or other proprietary information, and it is not clear at the present time how the FDA's disclosure policies may change in the future, if at all. Costly and time-consuming litigation could be necessary to enforce and determine the scope of our proprietary rights, and failure to obtain or maintain trade secret protection could adversely affect our competitive business position.

We may be subject to claims that our employees or consultants have wrongfully used or disclosed alleged trade secrets.

As is common in the biotechnology and pharmaceutical industries, we employ individuals who were previously employed at other biotechnology or pharmaceutical companies, including our competitors or potential competitors. Although we try to ensure that our employees and consultants do not use the proprietary information or know-how of others in their work for us, we may be subject to claims that we or our employees or consultants have inadvertently or otherwise used or disclosed trade secrets or other proprietary information of their former employers. Litigation may be necessary to defend against these claims. If we fail in defending any such claims, in addition to paying monetary damages, we could lose valuable intellectual property rights or personnel, which could adversely impact our business. Even if we are successful in defending against these claims, litigation could result in substantial costs and be a distraction to management.

Our intellectual property may not be sufficient to protect our product candidates from competition, which may negatively affect our business as well as limit our partnership or acquisition appeal.

We may be subject to competition despite the existence of intellectual property we license or may in the future own. We can give no assurances that our intellectual property claims will be sufficient to prevent third parties from designing around patents we own or license and developing and commercializing competitive products. The existence of competitive products that avoid our intellectual property could materially adversely affect our operating results and financial condition. Furthermore, limitations, or perceived limitations, in our intellectual property may limit the interest of third parties to partner, collaborate or otherwise transact with us, if third parties perceive a higher than acceptable risk to commercialization of our product candidates or future product candidates.

We may elect to sue a third party, or otherwise make a claim, alleging infringement or other violation of patents, trademarks, trade dress, copyrights, trade secrets, domain names or other intellectual property rights that we either own or license from a third party. If we do not prevail in enforcing our intellectual property rights in this type of litigation, we may be subject to:

- paying monetary damages related to the legal expenses of the third party;
- facing additional competition that may have a significant adverse effect on our product pricing, market share, business operations, financial condition, and the commercial viability of our product; and
- restructuring our company or delaying or terminating select business opportunities, including, but not limited to, research and development, clinical trial, and commercialization activities, due to a potential deterioration of our financial condition or market competitiveness.

A third party may also challenge the validity, enforceability or scope of the intellectual property rights that we license or own and the result of these challenges may narrow the scope or claims of or invalidate patents that are integral to our product candidates in the future. There can be no assurance that we will be able to successfully defend patents we own or license in an action against third parties due to the unpredictability of litigation and the high costs associated with intellectual property litigation, amongst other factors.

Intellectual property rights may be less extensive and enforcement more difficult in jurisdictions outside of the U.S. Therefore, we may not be able to protect our intellectual property and third parties may be able to market competitive products that may use some or all of our intellectual property.

Changes to patent law, including the Leahy-Smith America Invests Act of 2011 and the Patent Reform Act of 2009 and other future article of legislation, may substantially change the regulations and procedures surrounding patent applications, issuance of patents and prosecution of patents. We can give no assurances that the patents of our licensor can be defended or will protect us against future intellectual property challenges, particularly as they pertain to changes in patent law and future patent law interpretations.

Risks Related to Healthcare Compliance and Other Regulations

If we fail to comply with healthcare regulations, we could face substantial enforcement actions, including civil and criminal penalties and our business, operations and financial condition could be adversely affected.

We could be subject to healthcare fraud and abuse laws and patient privacy laws of both the federal government and the states in which we conduct our business. The laws include:

- the federal healthcare program anti-kickback law, which prohibits, among other things, persons from soliciting, receiving or providing remuneration, directly or indirectly, to induce either the referral of an individual, for an item or service or the purchasing or ordering of a good or service, for which payment may be made under federal healthcare programs such as the Medicare and Medicaid programs;
- federal false claims laws which prohibit, among other things, individuals or entities from knowingly presenting, or causing to be presented, claims for payment from Medicare, Medicaid, or other third-party payers that are false or fraudulent, and which may apply to entities like us which provide coding and billing information to customers;
- HIPAA which prohibits executing a scheme to defraud any healthcare benefit program or making false statements relating to healthcare matters and which also imposes certain requirements relating to the privacy, security and transmission of individually identifiable health information;
- the FDCA which among other things, strictly regulates drug manufacturing and product marketing, prohibits manufacturers from marketing drug products for off-label use and regulates the distribution of drug samples; and
- state law equivalents of each of the above federal laws, such as anti-kickback and false claims laws which may apply to items or services reimbursed by any third-party payer, including commercial insurers, and state laws governing the privacy and security of health information in certain circumstances, many of which differ from each other in significant ways and often are not preempted by federal laws, thus complicating compliance efforts.

If our operations are found to be in violation of any of the laws described above or any governmental regulations that apply to us, we may be subject to penalties, including civil and criminal penalties, damages, fines and the curtailment or restructuring of our operations. Any penalties, damages, fines, curtailment or restructuring of our operations could adversely affect our ability to operate our business and our financial results. Although compliance programs can mitigate the risk of investigation and prosecution for violations of these laws, the risks cannot be entirely eliminated. Any action against us for violation of these laws, even if we successfully defend against it, could cause us to incur significant legal expenses and divert management's attention from the operation of our business. Moreover, achieving and sustaining compliance with applicable federal and state privacy, security and fraud laws may prove costly.

Healthcare reform in the United States has been implemented in the past, and we expect further changes to be proposed in the future, leading to potential uncertainty in the healthcare industry. Violations of healthcare laws can have an adverse impact on our ability to advance our product candidates and our operating results.

In the United States, there have been, and continue to be, a number of legislative and regulatory changes and proposed changes to the healthcare system that could affect the future results of pharmaceutical manufactures' operations. In particular, there have been and continue to be a number of initiatives at the federal and state levels that seek to reduce healthcare costs. For example, the Affordable Care Act, or the ACA, which was originally enacted in March 2010 and subsequently amended, includes measures to significantly change the way healthcare is financed by both governmental and private insurers. Among the provisions of the ACA of greatest importance to the pharmaceutical and biotechnology industry are the following:

- an annual, nondeductible fee on any entity that manufactures or imports certain branded prescription drugs and biologic agents, apportioned among these entities according to their market share in certain government healthcare programs;

- implementation of the federal physician payment transparency requirements, sometimes referred to as the “Physician Payments Sunshine Act”;
- a licensure framework for follow-on biologic products;
- a new Patient-Centered Outcomes Research Institute to oversee, identify priorities in, and conduct comparative clinical effectiveness research, along with funding for such research;
- establishment of a Center for Medicare Innovation at the Centers for Medicare & Medicaid Services to test innovative payment and service delivery models to lower Medicare and Medicaid spending, potentially including prescription drug spending;
- an increase in the statutory minimum rebates a manufacturer must pay under the Medicaid Drug Rebate Program, to 23.1% and 13% of the average manufacturer price for most branded and generic drugs, respectively and capped the total rebate amount for innovator drugs at 100% of the Average Manufacturer Price;
- a new methodology by which rebates owed by manufacturers under the Medicaid Drug Rebate Program are calculated for certain drugs and biologics, including our product candidates, that are inhaled, infused, instilled, implanted or injected;
- extension of manufacturers’ Medicaid rebate liability to covered drugs dispensed to individuals who are enrolled in Medicaid managed care organizations;
- expansion of eligibility criteria for Medicaid programs by, among other things, allowing states to offer Medicaid coverage to additional individuals and by adding new mandatory eligibility categories for individuals with income at or below 133% of the federal poverty level, thereby potentially increasing manufacturers’ Medicaid rebate liability;
- a new Medicare Part D coverage gap discount program, in which manufacturers must agree to offer 50% point-of-sale discounts off negotiated prices of applicable brand drugs to eligible beneficiaries during their coverage gap period, as a condition for the manufacturer’s outpatient drugs to be covered under Medicare Part D; and
- expansion of the entities eligible for discounts under the Public Health program.

Some of the provisions of the ACA have yet to be implemented, and there have been legal and political challenges to certain aspects of the ACA. The former Trump administration issued certain executive orders and other directives designed to delay, circumvent, or loosen certain requirements mandated by the ACA. Concurrently, Congress considered legislation that would repeal or repeal and replace all or part of the ACA. While Congress has not passed repeal legislation, the Tax Cuts and Jobs Act of 2017 included a provision repealing, effective January 1, 2019, the tax-based shared responsibility payment imposed by the ACA on certain individuals who fail to maintain qualifying health coverage for all or part of a year that is commonly referred to as the “individual mandate.” Congress may consider other legislation to repeal or replace elements of the ACA.

Many of the details regarding the implementation of the ACA are yet to be determined, and at this time, the full effect that the ACA would have on a pharmaceutical manufacturer remains unclear. In particular, there is uncertainty surrounding the applicability of the biosimilars provisions under the ACA. This uncertainty is heightened by President Biden’s January 28, 2021 Executive Order on Strengthening Medicaid and the Affordable Care Act, which indicates that the Biden administration may significantly modify the ACA and potentially revoke any changes implemented by the Trump administration.

The FDA has issued several guidance documents, but no implementing regulations, on biosimilars. A number of biosimilar applications have been approved over the past few years. The regulations that are ultimately promulgated and their implementation are likely to have considerable impact on the way pharmaceutical manufacturers conduct their business and may require changes to current strategies. A biosimilar is a biological product that is highly similar to an approved drug notwithstanding minor differences in clinically inactive components, and for which there are no clinically meaningful differences between the biological product and the approved drug in terms of the safety, purity, and potency of the product.

Individual states have become increasingly aggressive in passing legislation and implementing regulations designed to control pharmaceutical and biological product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access, and marketing cost disclosure and transparency measures, and to encourage importation from other countries and bulk purchasing. Legally mandated price controls on payment amounts by third-party payors or other restrictions could harm a pharmaceutical manufacturer's business, results of operations, financial condition and prospects. In addition, regional healthcare authorities and individual hospitals are increasingly using bidding procedures to determine what pharmaceutical products and which suppliers will be included in their prescription drug and other healthcare programs. This could reduce ultimate demand for certain products or put pressure product pricing, which could negatively affect a pharmaceutical manufacturer's business, results of operations, financial condition and prospects.

It is also possible that President Biden will further reform the ACA and other federal programs in a manner that may impact our operations. For example, the Biden administration has indicated that a goal of its administration is to expand and support Medicaid and the ACA and to make high-quality healthcare accessible and affordable. The potential increase in patients covered by government funded insurance may impact our pricing. Further, it is possible that the Biden administration may further increase the scrutiny on drug pricing.

In addition, given recent federal and state government initiatives directed at lowering the total cost of healthcare, the Biden administration, Congress and state legislatures will likely continue to focus on healthcare reform, the cost of prescription drugs and biologics and the reform of the Medicare and Medicaid programs. For example, there have been several recent U.S. congressional inquiries and proposed federal and proposed and enacted state legislation designed to, among other things, bring more transparency to drug pricing, review the relationship between pricing and manufacturer patient programs, reduce the costs of drugs under Medicare and reform government program reimbursement methodologies for drug products. Further, in July 2020, former President Trump issued a number of executive orders that are intended to lower the costs of prescription drug products including one that directs HHS to finalize the rulemaking process on modifying the anti-kickback law safe harbors for discounts for plans, pharmacies, and pharmaceutical benefit managers. No assurance can be given whether these orders will remain in effect under the Biden administration.

While no one can predict the full outcome of any such legislation, it may result in decreased reimbursement for drugs and biologics, which may further exacerbate industry-wide pressure to reduce prescription drug prices. This could harm a pharmaceutical manufacturer's ability to generate revenue. Increases in importation or re-importation of pharmaceutical products from foreign countries into the United States could put competitive pressure on a pharmaceutical manufacturer's ability to profitably price products, which, in turn, could adversely affect business, results of operations, financial condition and prospects. A pharmaceutical manufacturer might elect not to seek approval for or market products in foreign jurisdictions in order to minimize the risk of re-importation, which could also reduce the revenue generated from product sales. It is also possible that other legislative proposals having similar effects will be adopted.

Furthermore, regulatory authorities' assessment of the data and results required to demonstrate safety and efficacy can change over time and can be affected by many factors, such as the emergence of new information, including on other products, changing policies and agency funding, staffing and leadership. We cannot be sure whether future changes to the regulatory environment will be favorable or unfavorable to our business prospects. For example, average review times at the FDA for marketing approval applications can be affected by a variety of factors, including budget and funding levels and statutory, regulatory and policy changes.

Our employees may engage in misconduct or other improper activities, including noncompliance with regulatory standards and requirements, which could cause significant liability for us and harm our reputation.

We are exposed to the risk of employee fraud or other misconduct, including intentional failures to comply with FDA regulations or similar regulations of comparable foreign regulatory authorities, provide accurate information to the FDA or comparable foreign regulatory authorities, comply with manufacturing standards we have established, comply with federal and state healthcare fraud and abuse laws and regulations and similar laws and regulations established and enforced by comparable foreign regulatory authorities, report financial information or data accurately or disclose unauthorized activities to us. Employee misconduct could also involve the improper use of information obtained in the course of clinical trials, which could result in regulatory sanctions and serious harm to our reputation. It is not always possible to identify and deter employee misconduct, and the precautions we take to detect and prevent this activity may not be effective in controlling unknown or unmanaged risks or losses

or in protecting us from governmental investigations or other actions or lawsuits stemming from a failure to be in compliance with such laws or regulations. If any such actions are instituted against us, and we are not successful in defending ourselves or asserting our rights, those actions could have a significant impact on our business and results of operations, including the imposition of significant civil, criminal and administrative penalties, damages, fines, imprisonment, exclusion from government funded healthcare programs, such as Medicare and Medicaid, and integrity oversight and reporting obligations.

We may rely on government funding and collaboration with government entities for our vaccine development, which adds uncertainty to our research and development efforts and may impose requirements that increase the costs of development, commercialization and production of any programs developed under those government-funded programs.

Because we anticipate the resources necessary to develop our vaccine product candidates will be substantial, we may explore funding and development collaboration opportunities with the U.S. government and its agencies. For example, we may apply for certain grant funding from BARDA, the NIH or other government agencies to further the research, development, manufacture, testing, and regulatory approval of our vaccine product candidates. We have no control or input over whether an application for BARDA grant funding or any other funding will be accepted or approved, in full or in part, and we cannot provide investors with any assurances that we will receive such funding.

Contracts and grants funded by the U.S. government and its agencies, contain provisions that reflect the government's substantial rights and remedies, many of which are not typically found in commercial contracts, including powers of the government to:

- reduce or modify the government's obligations under such agreements without the consent of the other party;
- claim rights, including Intellectual Property rights, in products and data developed under such agreements;
- audit contract-related costs and fees, including allocated indirect costs;
- suspend the contractor or grantee from receiving new contracts pending resolution of alleged violations of procurement laws or regulations.
- impose U.S. manufacturing requirements for products that embody inventions conceived or first reduced to practice under such agreements;
- suspend or debar the contractor or grantee from doing future business with the government;
- control and potentially prohibit the export of products;
- pursue criminal or civil remedies under the False Claims Act, False Statements Act, and similar remedy provisions specific to government agreements; and
- limit the government's financial liability to amounts appropriated by the U.S. Congress on a fiscal-year basis, thereby leaving some uncertainty about the future availability of funding for a program even after it has been funded for an initial period.

If we received such grants or agreements, we may not have the right to prohibit the U.S. government from using certain technologies developed by us, and we may not be able to prohibit third-parties, including our competitors, from using those technologies in providing products and services to the U.S. government. Further, under such agreements we could be subject to obligations to and the rights of the U.S. government set forth in the Bayh-Dole Act of 1980, meaning the U.S. government may have rights in certain inventions developed under these government-funded agreements, including a non-exclusive, non-transferable, irrevocable worldwide license to use inventions for any governmental purpose. In addition, the U.S. government could have the right to require us to grant exclusive, partially exclusive, or nonexclusive licenses to any of these inventions to a third party if it determines that: (i) adequate steps have not been taken to commercialize the invention; (ii) government action is necessary to meet public health or safety needs; or (iii) government action is necessary to meet requirements for public use under federal regulations, also referred to as "march-in rights." Although the U.S. government's historic restraint with respect to these rights indicates they are unlikely to be used, any exercise of the march-in rights could harm

our competitive position, business, financial condition, results of operations, and prospects. In the event we would be subject to the U.S. government's exercise such march-in rights, we may receive compensation that is deemed reasonable by the U.S. government in its sole discretion, which may be less than what we might be able to obtain in the open market.

Additionally, the U.S. government requires that any products embodying any invention generated through the use of U.S. government funding be manufactured substantially in the United States. The manufacturing preference requirement can be waived if the owner of the intellectual property can show that reasonable but unsuccessful efforts have been made to grant licenses on similar terms to potential licensees that would be likely to manufacture substantially in the United States or that under the circumstances domestic manufacture is not commercially feasible. This preference for U.S. manufacturers may limit our ability to contract with non-U.S. manufacturers for products covered by such intellectual property.

Although we may need to comply with some of these obligations, not all of the aforementioned obligations may be applicable to us unless and only to the extent that we receive a government grant, contract or other agreement. However, as an organization, we are relatively new to government contracting and new to the regulatory compliance obligations that such contracting entails. If we were to fail to maintain compliance with those obligations, we may be subject to potential liability and to termination of our contracts, which may have a materially adverse effect on our ability to develop our vaccine product candidates.

We are subject to U.S. and certain foreign export and import controls, sanctions, embargoes, anti-corruption laws and anti-money laundering laws and regulations. Compliance with these legal standards could impair our ability to compete in domestic and international markets. We can face criminal liability and other serious consequences for violations, which can harm our business.

We are subject to export control and import laws and regulations, including the U.S. Export Administration Regulations, U.S. Customs regulations, various economic and trade sanctions regulations administered by the U.S. Treasury Department's Office of Foreign Assets Controls, the U.S. Foreign Corrupt Practices Act of 1977, as amended, the U.S. domestic bribery statute contained in 18 U.S.C. § 201, the U.S. Travel Act, the USA PATRIOT Act and other state and national anti-bribery and anti-money laundering laws in the countries in which we conduct activities. Anti-corruption laws are interpreted broadly and prohibit companies and their employees, agents, contractors, and other collaborators from authorizing, promising, offering or providing, directly or indirectly, improper payments or anything else of value to recipients in the public or private sector. We may engage third parties for clinical trials outside of the United States, to sell our products abroad once we enter a commercialization phase and/or to obtain necessary permits, licenses, patent registrations, and other regulatory approvals. We have direct or indirect interactions with officials and employees of government agencies or government-affiliated hospitals, universities and other organizations. We can be held liable for the corrupt or other illegal activities of our employees, agents, contractors and other collaborators, even if we do not explicitly authorize or have actual knowledge of such activities. Any violations of the laws and regulations described above may result in substantial civil and criminal fines and penalties, imprisonment, the loss of export or import privileges, debarment, tax reassessments, breach of contract and fraud litigation, reputational harm and other consequences.

Risks Related to Owning our Common Stock and this Offering

The market price of our common stock may be highly volatile, and you could lose all or part of your investment.

Prior to this offering, there was no public market for shares of our common stock. The offering price for the shares of our common stock sold in this offering will be determined by negotiation between the underwriters and us. This price may not reflect the market price of our common stock following this offering. As a result, the trading price of our common stock is likely to be volatile, which may prevent you from being able to sell your shares at or above the public offering price. 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. Such broad market and industry factors may negatively affect the market price of our common stock, regardless of our actual operating performance.

We may be subject to securities litigation, which is expensive and could divert our management's attention.

The market price of our securities may be volatile, and in the past, companies that have experienced volatility in the market price of their securities have been subject to securities class action litigation. We may be the target of this type of litigation in the future. Securities litigation against us could result in substantial costs and divert our management's attention from other business concerns, which could seriously harm our business.

Our Amended and Restated Certificate of Incorporation will require, to the fullest extent permitted by law, that derivative actions brought in our name, actions against our directors, officers, other employees or stockholders for breach of fiduciary duty and other similar actions may be brought only in the Court of Chancery in the State of Delaware and, if brought outside of Delaware, the stockholder bringing the suit will be deemed to have consented to service of process on such stockholder's counsel, which may have the effect of discouraging lawsuits against our directors, officers, other employees or stockholders.

Our Amended and Restated Certificate of Incorporation will require, to the fullest extent permitted by law, that derivative actions brought in our name, actions against our directors, officers, other employees or stockholders for breach of fiduciary duty and other similar actions may be brought only in the Court of Chancery in the State of Delaware and, if brought outside of Delaware, the stockholder bringing the suit will be deemed to have consented to service of process on such stockholder's counsel 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, (C) for which the Court of Chancery does not have subject matter jurisdiction, or (D) any action arising under the Securities Act, as to which the Court of Chancery and the federal district court for the District of Delaware shall have concurrent jurisdiction.

Any person or entity purchasing or otherwise acquiring any interest in shares of our capital stock shall be deemed to have notice of and consented to the forum provisions in our Amended and Restated Certificate of Incorporation. This choice of forum provision may make it more costly for a stockholder to bring a claim, and it may also limit a stockholder's ability to bring a claim in a judicial forum that it finds favorable for disputes with us or any of our directors, officers, other employees or stockholders, which may discourage lawsuits with respect to such claims, although our stockholders cannot waive our compliance with federal securities laws and the rules and regulations thereunder. Alternatively, if a court were to find the choice of forum provision contained in our Amended and Restated Certificate of Incorporation to be inapplicable or unenforceable in an action, we may incur additional costs associated with resolving such action in other jurisdictions, which could harm our business, operating results and financial condition.

Our Amended and Restated Certificate of Incorporation will provide that the exclusive forum provision will be applicable to the fullest extent permitted by applicable law. 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 of 1933, as amended, 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.

We have broad discretion in the use of the net proceeds from this offering and may invest or spend the proceeds in ways with which you disagree or that may not yield a return.

While we set forth our anticipated use for the net proceeds from this offering in the section titled "Use of Proceeds," our management will have broad discretion on how to use and spend any proceeds that we receive from this offering and may, depending on the outcomes of our preclinical studies and other research, such as limited efficacy, higher than anticipated toxicity, use the proceeds in manners that differ from the anticipated uses set forth in this prospectus, such accelerating development of existing programs, expanding our current pipeline to include additional programs based on our platform, to in license additional programs identified by management or other such activities. We expect to use the net proceeds from this offering, together with our existing cash and cash equivalents, to advance the development of our preclinical product candidates and to fund working capital, including general operating expenses. Investors in this offering will need to rely upon the judgment of our management with respect to the use of proceeds with only limited information concerning management's specific intentions. It is possible that we may decide in the future not to use the proceeds of this offering in the manner described in this offering. Our management may spend a portion or all of the net proceeds from this offering in ways that holders of our common stock may not desire or that may not yield a significant return or any return at all. Investors will receive no notice or vote regarding any such change and may not agree with our decision on how to use such proceeds. If we fail to utilize the proceeds we receive from this offering effectively, our business and financial condition could be harmed and we may need to seek additional financing sooner than expected. Pending their use, we may also invest the net proceeds from this offering in a manner that does not produce income or that loses value.

There is no existing market for our common stock and we do not know if one will develop to provide you with adequate liquidity.

Prior to this offering, there has not been a public market for our common stock. Although we intend to apply to have our common stock listed on Nasdaq, an active trading market for our common stock may never develop or be sustained following this offering. You may not be able to sell your shares quickly or at the market price if trading in our common stock is not active. The initial public offering price for the shares will be determined by negotiations between us and the underwriters and may not be indicative of prices that will prevail in the trading market. You may not be able to sell your shares of our common stock at or above the price you paid in the offering. As a result, you could lose all or part of your investment. Further, an inactive market may also impair our ability to raise capital by selling shares of our common stock and 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.

After this offering, it is anticipated that our officers and directors, together with holders of 5% or more of our outstanding common stock before this offering and their respective affiliates, will beneficially own or control 7,598,460 shares of our common stock, which in the aggregate will represent approximately 69.6% of the outstanding shares of our common stock, or 67.6% if the underwriters' option to purchase additional shares is exercised in full. 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.

Our failure to meet the continued listing requirements of Nasdaq could result in a de-listing of our common stock.

If, after listing, we fail to satisfy the continued listing requirements of Nasdaq, such as the corporate governance requirements or the minimum closing bid price requirement, Nasdaq may take steps to de-list our common stock. Such a de-listing would likely have a negative effect on the price of our common stock and would impair your ability to sell or purchase our common stock when you wish to do so. In the event of a de-listing, we would take actions to restore our compliance with Nasdaq Marketplace Rules, but our common stock may not be listed again, stabilize the market price or improve the liquidity of our common stock, prevent our common stock from dropping below the Nasdaq minimum bid price requirement or prevent future non-compliance with the Nasdaq Marketplace Rules.

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 obtain or 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 shares by existing stockholders could cause our stock price to decline.

If our existing stockholders sell, or indicate an intent to sell, substantial amounts of our common stock in the public market after the 180-day 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. Based on 8,691,576 shares of common stock outstanding as of October 31, 2021 (after giving effect to the Pre-IPO Stock Split and conversion of all outstanding shares of convertible preferred stock and accrued dividends, pursuant to an optional conversion which has been approved by requisite holders of our series seed preferred stock, into an aggregate of up 5,491,576 shares of common stock, upon the completion of this offering, we will have outstanding 10,913,798 shares of common stock, assuming no exercise of outstanding options or warrants, including the Representative's warrants. Of these shares, 2,222,222 shares of common stock, plus any shares sold pursuant to the underwriters' option to purchase additional shares, will be immediately 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 the lock-up agreements described in the "Underwriting" section of this prospectus.

After the lock-up agreements pertaining to this offering expire and based on shares outstanding after this offering, an additional 8,691,576 shares will be eligible for sale in the public market. In addition, upon issuance (after accounting for the Pre-IPO Stock Split), the 780,640 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.

If you purchase shares of common stock in this offering, you will suffer immediate dilution of your investment.

The public offering price of our common stock will be substantially higher than the net tangible book value per share of our common stock. Therefore, if you purchase shares of our common stock in this offering, you will pay a price per share that substantially exceeds our net tangible book value per share after this offering. To the extent shares subsequently are issued under outstanding stock options, you will incur further dilution. Based on an assumed initial public offering price of $9.00 per share, which is the midpoint of the price range set forth on the cover page of this prospectus, and after giving effect to the Pre-IPO Stock Split and conversion of all outstanding shares of convertible preferred stock and accrued dividends, pursuant to an optional conversion which has been approved by requisite holders of our series seed preferred stock, you will experience immediate dilution of $7.04 per share, representing the difference between our pro forma net tangible book value per share, after giving effect to this offering, and the assumed initial public offering price. In addition, purchasers of common stock in this offering will have contributed approximately 74.1% of the aggregate price paid by all purchasers of our stock but will own only approximately 20.6% of our common stock outstanding after this offering.

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, 2026 (the fiscal year-end following the fifth anniversary of the completion of our initial public offering), 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 $1.07 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.

We will incur significant costs as a result of operating as a public company and our management expects to devote substantial time to public company compliance programs.

As a public company, we will incur significant legal, accounting and other expenses due to our compliance with regulations and disclosure obligations applicable to us, including compliance with the Sarbanes-Oxley Act, as well as rules implemented by the SEC and Nasdaq. Shareholder activism, the current political environment and the current high level of government intervention and regulatory reform may lead to substantial new regulations and disclosure

obligations, which may lead to additional compliance costs and impact, in ways we cannot currently anticipate, the manner in which we operate our business. Our management and other personnel will devote a substantial amount of time to these compliance programs and monitoring of public company reporting obligations and as a result of the new corporate governance and executive compensation related rules, regulations and guidelines prompted by the Dodd-Frank Act and further regulations and disclosure obligations expected in the future, we will likely need to devote additional time and costs to comply with such compliance programs and rules. These rules and regulations will cause us to incur significant legal and financial compliance costs and will make some activities more time-consuming and costly.

To comply with the requirements of being a public company, we may need to undertake various actions, including implementing new internal controls and procedures and hiring new accounting or internal audit staff. The Sarbanes-Oxley Act requires that we maintain effective disclosure controls and procedures and internal control over 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 file with the SEC is recorded, processed, summarized and reported within the time periods specified in SEC rules and forms, and that information required to be disclosed in reports under the Securities Exchange Act of 1934, as amended, or the Exchange Act, is accumulated and communicated to our principal executive and financial officers. Our current controls and any new controls that we develop may become inadequate and weaknesses in our internal control over financial reporting may be discovered in the future. Any failure to develop or maintain effective controls when we become subject to this requirement could negatively impact the results of periodic management evaluations and annual independent registered public accounting firm attestation reports regarding the effectiveness of our internal control over financial reporting that we may be required to include in our periodic reports we will file with the SEC under Section 404 of the Sarbanes-Oxley Act of 2002, or the Sarbanes-Oxley Act, harm our operating results, cause us to fail to meet our reporting obligations or result in a restatement of our prior period financial statements. In the event that we are not able to demonstrate compliance with the Sarbanes-Oxley Act, that our internal control over financial reporting is perceived as inadequate or that we are unable to produce timely or accurate financial statements, investors may lose confidence in our operating results and the price of our common stock could decline. In addition, if we are unable to continue to meet these requirements, we may not be able to remain listed on Nasdaq.

Our management team has limited experience managing a public company.

Most members of our management team have limited experience managing a publicly-traded company, interacting with public company investors and complying with the increasingly complex laws pertaining to public companies. Our management team may not successfully or efficiently manage our transition to being a public company subject to significant regulatory oversight and reporting obligations under the federal securities laws and the continuous scrutiny of securities analysts and investors. These new obligations and constituents will require significant attention from our senior management and could divert their attention away from the day-to-day management of our business, which could adversely affect our business, financial condition and operating results.

If we fail to maintain an effective system of internal controls, we may not be able to accurately report our financial results or prevent fraud which could subject us to regulatory sanctions, harm our business and operating results and cause the trading price of our stock to decline.

Effective internal controls required under Section 404 of the Sarbanes-Oxley Act, are necessary for us to provide reliable financial reports and effectively prevent fraud. If we cannot provide reliable financial reports or prevent fraud, our business, reputation and operating results could be harmed. We have discovered, and may in the future discover, areas of our internal controls that need improvement. We cannot be certain that the measures we have taken or intend to take will ensure that we maintain adequate controls over our financial processes and reporting in the future. Any failure to implement required new or improved controls or difficulties encountered in their implementation could subject us to regulatory sanctions, harm our business and operating results or cause us to fail to meet our reporting obligations. Inferior internal controls could also harm our reputation and cause investors to lose confidence in our reported financial information, which could have a negative impact on the trading price of our stock.

If securities or industry analysts do not publish research, or publish inaccurate or unfavorable research, about our business, our stock price and trading volume could decline.

The trading market for our common stock will depend, in part, on the research and reports that securities or industry analysts publish about us or our business. Securities and industry analysts do not currently, and may never, publish research on us. If no securities or industry analysts commence coverage of us, the price for our common stock could be negatively impacted. In the event securities or industry analysts initiate coverage, if one or more of the analysts who cover us downgrade our common stock or publish inaccurate or unfavorable research about our business, our stock price could decline. In addition, if our operating results fail to meet the forecast of analysts, our stock price could decline. If one or more of these analysts cease coverage of us or fail to publish reports on us regularly, demand for our common stock could decrease, which might cause our stock price and trading volume to decline.

Our Amended and Restated Certificate of Incorporation and our Amended and Restated Bylaws to be adopted in connection with this offering, 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 will authorize 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 will be your sole source of gain for the foreseeable future.

A possible "short squeeze" due to a sudden increase in demand of our common stock that largely exceeds supply may lead to price volatility in our common stock.

Following this offering, investors may purchase our common stock to hedge existing exposure in our common stock or to speculate on the price of our common stock. Speculation on the price of our common stock may involve long and short exposures. To the extent aggregate short exposure exceeds the number of shares of our common stock available for purchase in the open market, investors with short exposure may have to pay a premium to repurchase our common stock for delivery to lenders of our common stock. Those repurchases may in turn, dramatically increase the price of our common stock until investors with short exposure are able to purchase additional common shares to cover their short position. This is often referred to as a "short squeeze." A short squeeze could lead to volatile price movements in our common stock that are not directly correlated to the performance or prospects of our company and once investors purchase the shares of common stock necessary to cover their short position the price of our common stock may decline.

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," "Risk Factors," "Management's Discussion and Analysis of Financial Condition and Results of Operations" and "Business," 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.” 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 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 as exhibits to the registration statement of which this prospectus forms a part 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 estimate that the net proceeds to us from our issuance and sale of 2,222,222 shares of common stock in this offering will be approximately $17.5 million (or $20.2 million if the underwriters exercise their option to purchase additional shares of common stock in full), based upon an assumed initial public offering price of $9.00 per share, which is the mid-point of the price range set forth on the cover page of this prospectus, and after deducting underwriting discounts and commissions and estimated offering expenses payable by us.

Each $1.00 increase or decrease in the assumed initial public offering price of $9.00 per share, which is the midpoint of the price range set forth on the cover page of this prospectus, after deducting underwriting discounts and commissions and estimated offering expenses payable by us, would increase or decrease, as applicable, the net proceeds to us from this offering by approximately $2.0 million, assuming the number of shares offered by us, as set forth on the cover page of this prospectus, remains the same. We may also increase or decrease the number of shares we are offering. Each increase or decrease of 1.0 million in the number of shares we are offering at the assumed initial public offering price of $9.00 per share, which is the midpoint of the price range set forth on the cover page of this prospectus, after deducting underwriting discounts and commissions and estimated offering expenses payable by us, would increase or decrease, as applicable, the net proceeds to us from this offering by approximately $8.3 million, assuming the assumed initial public offering price remains the same.

We intend to use the net proceeds from this offering as follows:

- approximately 60% to fund our research and development activities for BWV-101, BWV-102, BWV-201, BWV-301 and BWV 302, including manufacturing and pre-IND enabling studies;
- approximately 20% to fund Phase I clinical trials and regulatory review process for vaccine candidates, with an initial focus on BWV-101, BWV-102, BWV-201, subject to the outcomes of our preclinical studies; and
- the remainder for working capital and other general corporate purposes, including the additional costs associated with being a public company.

The foregoing is set forth based on the order of priority for each purpose and represents our intentions based upon our current plans and business conditions, which could change in the future as our plans and business conditions evolve. While our anticipated use for the proceeds of this offering is set forth above, our management will have broad discretion on how to use and spend any proceeds that we receive from this offering and may, depending on the outcomes of our preclinical studies and other research, such as limited efficacy, higher than anticipated toxicity, use such proceeds in manners that differ from such anticipated uses. Such alternative uses of the proceeds include accelerating development of existing programs, expanding our current pipeline to include additional programs based on our platform and in-licensing additional programs identified by management.

We believe opportunities may exist from time to time to expand our current business through the acquisition or in-license of complementary products and product candidates. While we have no current agreements or commitments for any specific acquisitions or in-licenses at this time, we may use a portion of the net proceeds for these purposes.

Pending our use of the net proceeds from this offering, we intend to invest the net proceeds in a variety of capital preservation investments, including short-term, investment-grade, interest-bearing instruments and U.S. government securities.

DIVIDEND POLICY

We have never declared or paid any cash dividends on our capital stock. We do not anticipate paying cash dividends on our common stock in the foreseeable future. We currently intend to retain all available funds and any future earnings to support our operations and finance the growth and development of our business. Any future determination related to our dividend policy will be made at the discretion of our board of directors and will depend upon, among other factors, our results of operations, financial condition, capital requirements, contractual restrictions, business prospects, the requirements of current or then-existing debt instruments and other factors our board of directors may deem relevant.

CAPITALIZATION

The following table sets forth our cash and capitalization as of June 30, 2021:

- on an actual basis;
- on a pro forma basis to reflect (i) the conversion of all outstanding shares of convertible preferred stock and accrued dividends into an aggregate of up 5,347,420 shares of common stock, pursuant to an optional conversion, effective upon consummation of this offering, which has been approved by requisite holders of our series seed preferred stock, and (ii) the Pre-IPO Stock Split, which is subject to the approval of our stockholders and board of directors;
- on a pro forma as adjusted basis to give further effect to our issuance and sale of shares of common stock in this offering at an assumed initial public offering price of $ per share, which is the midpoint of the price range set forth on the cover page of this prospectus, after deducting the underwriting discounts and commissions and estimated offering expenses payable by us.

The pro forma and pro forma as adjusted information below is illustrative only and our capitalization following the completion of this offering is subject to adjustment based on the initial public offering price of our common stock and other terms of this offering determined at pricing. You should read the following table in conjunction with "Use of Proceeds," "Selected Financial Data," "Management's Discussion and Analysis of Financial Condition and Results of Operations," "Description of Capital Stock" and other financial information contained in this prospectus, including the financial statements and related notes appearing elsewhere in this prospectus.

	As of June 30, 2021		
	Actual (unaudited)	Pro Forma (unaudited)	Pro Forma As Adjusted[1] (unaudited)
Cash	$ 3,669,468	$ 3,669,468	
Total debt	—	—	
Stockholders' equity:			
Preferred Stock: 1,150,000 Series Seed preferred shares designated; 1,146,138 Series Seed preferred shares issued and outstanding at June 30, 2021; 10,000,000 shares of preferred stock authorized, 0 issued and outstanding pro forma and shares authorized, issued and outstanding pro forma as adjusted (unaudited)	11	—	
Common stock, $0.00001 par value, 2,300,000 shares authorized; 800,000 shares outstanding at June 30, 2021; and 150,000,000 shares authorized, 8,547,420 shares issued and outstanding pro forma and shares authorized, issued and outstanding pro forma as adjusted (unaudited)	8	85	
Additional paid-in-capital	7,349,732	7,349,666	
Accumulated deficit	(3,657,391)	(3,657,391)	
Total stockholders' equity	3,692,360	3,692,360	
Total capitalization	3,692,360	3,692,360	

(1) A $1.00 increase or decrease in the assumed initial public offering price of $9.00 per share, which is the midpoint of the price range set forth on the cover page of this prospectus, would increase or decrease, as applicable, each of cash and cash equivalents, additional paid-in capital, total stockholders' (deficit) equity and total capitalization by approximately $ million, assuming the number of shares offered by us, as stated on the cover page of this prospectus, remains unchanged and after deducting underwriting discounts and commissions and estimated offering expenses payable by us. Similarly, each increase or decrease of 1.0 million in the number of shares we are offering would increase or decrease, as applicable, each of cash and cash equivalents, additional paid-in capital, total stockholders' (deficit) equity and total capitalization by $ million, assuming the assumed initial public offering price of $9.00 per share, which is the midpoint of the price range set forth on the cover page of this prospectus, remains the same and after deducting underwriting discounts and commissions and estimated offering expenses payable by us.

The number of shares of our common stock to be outstanding after this offering is based on 8,547,420 shares of common stock outstanding as of June 30, 2021 (after giving effect to (i) the conversion of all outstanding shares of convertible preferred stock and accrued dividends into an aggregate of up 5,347,420 shares of common stock, pursuant to an optional conversion, effective upon consummation of this offering, which has been approved by requisite holders of our series seed preferred stock, and (ii) the Pre-IPO Stock Split), and excludes:

- 780,640 shares of common stock issuable upon the exercise of outstanding stock options under our 2019 Equity Incentive Plan, or the 2019 Plan, as of June 30, 2021, after giving effect to the Pre-IPO Stock Split;
- 617,360 shares of our common stock reserved for future issuance under the 2019 Plan, which, upon adoption of our 2021 Equity Incentive Plan, or the 2021 Plan, will be issuable under the 2021 Plan, after giving effect to the Pre-IPO Stock Split;
- 111,111 shares of our common stock issuable upon the exercise of the warrant issued to the representative of the underwriters at the closing of this offering.

DILUTION

If you invest in our common stock in this offering, your ownership interest will be immediately diluted to the extent of the difference between the initial public offering price per share of our common stock and the pro forma as adjusted net tangible book value per share of our common stock immediately after this offering. Net tangible book value per share of common stock is determined by dividing our total tangible assets less total liabilities by the number of outstanding shares of our common stock.

Our historical net tangible book value as of June 30, 2021 was approximately $3.7 million or $4.62 per share of common stock. Our pro forma net tangible book value as of June 30, 2021 was $3.7 million or $0.43 per share of common stock. Our pro forma net tangible book value represents the amount of our total tangible assets less our total liabilities, after giving effect to the Pre-IPO Stock Split and conversion of all outstanding shares of convertible preferred stock and accrued dividends, pursuant to an optional conversion which has been approved by requisite holders of our series seed preferred stock.

Pro forma as adjusted net tangible book value is our pro forma net tangible book value, after giving further effect to (i) the sale of 2,222,222 shares of our common stock in this offering at an assumed initial public offering price of $9.00 per share, which is the midpoint of the price range set forth on the cover page of this prospectus, after deducting underwriting discounts and commissions and estimated offering expenses payable by us, and (ii) the application of the net proceeds from this offering as described in the section of this prospectus entitled “Use of Proceeds.” This amount represents an immediate increase in pro forma net tangible book value of $1.53 per share to our existing stockholders, and an immediate dilution of $7.04 per share to new investors participating in this offering.

The following table illustrates this dilution on a per share basis to new investors:

Assumed initial public offering price per share		$ 9.00
Historical net tangible book value per share as of June 30, 2021	$ 4.62	
Pro forma net tangible book value per share as of June 30, 2021, before giving effect to this offering	0.43	
Increase in pro forma net tangible book value per share attributable to new investors participating in this offering	1.53	
Pro forma as adjusted net tangible book value per share after this offering		1.96
Dilution in pro forma net tangible book value per share to new investors participating in this offering		$ 7.04

A $1.00 increase or decrease in the assumed initial public offering price of $9.00 per share, which is the midpoint of the price range set forth on the cover page of this prospectus, would increase or decrease, as applicable, the pro forma as adjusted net tangible book value per share after this offering by approximately $0.19 per share and decrease or increase, as appropriate, the dilution in pro forma net tangible book value per share to investors participating in this offering by approximately $0.81 per share, assuming that the number of shares offered by us, as set forth on the cover page of this prospectus, remains the same and after deducting underwriting discounts and commissions and estimated offering expenses payable by us.

An increase of 1.0 million shares in the number of shares offered by us, as set forth on the cover page of this prospectus, would increase our pro forma as adjusted net tangible book value after this offering by $0.54 per share and decrease the dilution to new investors purchasing common stock in this offering by $0.54 per share, assuming no change in the assumed initial public offering price per share and after deducting estimated underwriting discounts and commissions. A decrease of 1.0 million shares in the number of shares offered by us would decrease the pro forma as adjusted net tangible book value after this offering by $0.65 per share and increase the dilution to new investors purchasing common stock in this offering by $0.65 per share, assuming no change in the assumed initial public offering price per share and after deducting estimated underwriting discounts and commissions.

The pro forma information discussed above is illustrative only and will change based on the actual initial public offering price, number of shares and other terms of this offering determined at pricing.

If the underwriters exercise in full their option to purchase 333,333 additional shares of our common stock in this offering, the pro forma as adjusted net tangible book value will increase to $2.15 per share, representing an immediate increase in pro forma net tangible book value to existing stockholders of $0.19 per share and an immediate dilution of $0.19 per share to new investors participating in this offering.

The following table sets forth, as of June 30, 2021, on the pro forma as adjusted basis described above, the differences between our existing stockholders and the purchasers of shares of common stock in this offering with respect to the number of shares of common stock purchased from us, the total consideration paid to us and the weighted average price paid per share paid to us, based on an assumed initial public offering price of $9.00 per share, which is the midpoint of the price range set forth on the cover page of this prospectus, before deducting underwriting discounts and commissions and estimated offering expenses payable by us:

	Shares Purchased		Total Consideration		Weighted Average Price per Share
	Number	Percent	Amount	Percent	
Existing stockholders	8,547,420	79.4%	$ 6,979,977	25.9%	$ 0.82
New investors	2,222,222	20.6	19,999,998	74.1	9.00
Total	10,769,642	100%	$ 26,979,975	100%	

If the underwriters exercise in full their option to purchase additional shares of our common stock in this offering, the number of shares held by existing stockholders will be reduced to 77.0% of the total number of shares of common stock that will be outstanding upon completion of this offering, and the number of shares of common stock held by new investors participating in this offering will be further increased to 23.0% of the total number of shares of common stock that will be outstanding upon completion of the offering.

We may choose to raise additional capital through the sale of equity or equity-linked securities due to market conditions or strategic considerations even if we believe we have sufficient funds for our current or future operating plans. To the extent that any options are issued under our equity incentive plan or we issue additional shares of common stock or equity-linked securities in the future, there will be further dilution to investors purchasing in this offering.

The number of shares of our common stock to be outstanding after this offering is based on 8,547,420 shares of common stock outstanding as of June 30, 2021 (after giving effect to (i) the conversion of all outstanding shares of convertible preferred stock and accrued dividends into an aggregate of up 5,347,420 shares of common stock, pursuant to an optional conversion, effective upon consummation of this offering, which has been approved by requisite holders of our series seed preferred stock, and (ii) the Pre-IPO Stock Split), and excludes:

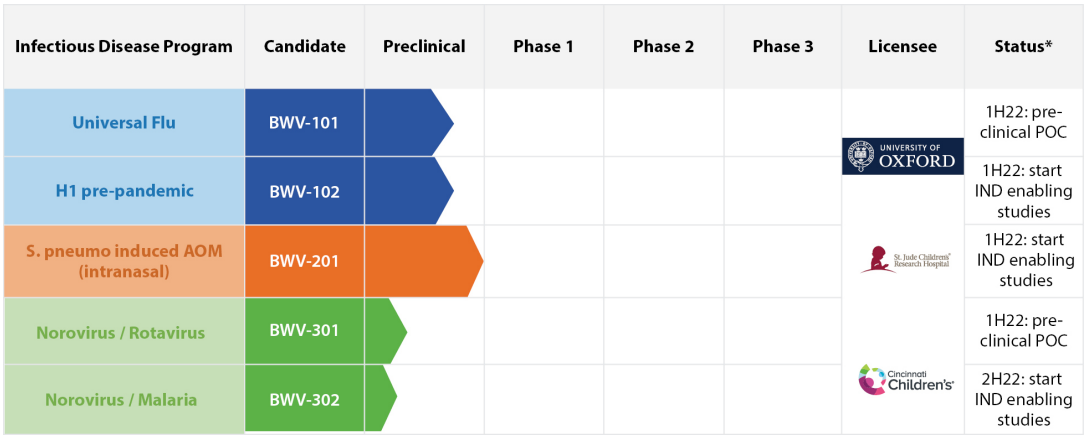
- 780,640 shares of common stock issuable upon the exercise of outstanding stock options under our 2019 Equity Incentive Plan, or the 2019 Plan, as of June 30, 2021, after giving effect to the Pre-IPO Stock Split;
- 619,360 shares of our common stock reserved for future issuance under the 2019 Plan, which, upon adoption of our 2021 Equity Incentive Plan, or the 2021 Plan, will be issuable under the 2021 Plan, after giving effect to the Pre-IPO Stock Split; and
- 111,111 shares of our common stock issuable upon the exercise of the warrant issued to the representative of the underwriters at the closing of this offering.

MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

You should read the following discussion of our financial condition and results of operations in conjunction with "Selected Financial Data" and our financial statements and related notes included elsewhere in this prospectus. This discussion and analysis and other parts of this prospectus contain forward-looking statements based upon current beliefs, plans and expectations that involve risks, uncertainties and assumptions. Our actual results and the timing of selected events could differ materially from those anticipated in these forward-looking statements as a result of several factors, including those set forth under "Risk Factors" and elsewhere in this prospectus. You should carefully read the "Risk Factors" section of this prospectus to gain an understanding of the important factors that could cause actual results to differ materially from our forward-looking statements. Please also see the section entitled "Cautionary Note Regarding Forward-Looking Statements and Industry and Market Data" in this prospectus.

Overview

We are a biotechnology company focused on the research and development of transformational vaccines to prevent infectious diseases worldwide. Our versatile vaccine platform has unique molecular properties that enables delivery of various antigens, which can be utilized to develop singular or multi-targeted vaccines. Our lead influenza (flu) vaccine program uses proprietary technology to identify specific epitopes, or proteins of antigens, with cross-reactive properties, that enable the potential development of a universal flu vaccine. We are focused on developing novel vaccines that induce durable and long-term immunity. 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.



* Pipeline projections are based upon the completion of the initial public offering.

Since our inception in October 2018, 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, acquiring 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. We do not have any products approved for sale and have not generated any revenue from product sales. To date, we have financed our operations primarily with proceeds from our sale of preferred securities to seed investors. We will continue to require additional capital to develop our vaccine candidates and fund operations for the foreseeable future. Accordingly, until such time as we can generate significant revenue from sales of our vaccine candidates, if ever, 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.

We have incurred net losses since inception and expect to continue to incur net losses in the foreseeable future. Our net losses may fluctuate significantly from quarter-to-quarter and year-to-year, depending in large part on the timing of our preclinical studies, clinical trials and manufacturing activities, and our expenditures on other research

and development activities. As of June 30, 2021, the Company had working capital of approximately $3.6 million and an accumulated deficit of approximately $3.7 million. We will need to raise additional capital to fund our planned operations within one year from the issuance date of our financial statements.

While we believe that we can raise additional capital to fund our planned operations, until we generate revenue sufficient to support self-sustaining cash flows, if ever, we will need to raise additional capital to fund our continued operations, including our product development and commercialization activities related to our current and future products. There can be no assurance that additional capital will be available to us on acceptable terms, or at all, or that we will ever generate revenue sufficient to provide for self-sustaining cash flows. These circumstances raise substantial doubt about our ability to continue as a going concern. The accompanying financial statements do not include any adjustment that might be necessary if the Company is unable to continue as a going concern.

We do not expect to generate any revenue from commercial product sales unless and until we successfully complete development and obtain regulatory approval for one or more of our vaccine candidates, which we expect will take a number of years. We expect our expenses will increase substantially in connection with our ongoing activities, as we:

- advance vaccine candidates through preclinical studies and clinical trials;
- require the manufacture of supplies for our preclinical studies and clinical trials;
- pursue regulatory approval of vaccine candidates;
- hire additional personnel;
- operate as a public company.
- acquire, discover, validate and develop additional vaccine candidates; and
- obtain, maintain, expand and protect our intellectual property portfolio.

We rely and will continue to rely on third parties in the conduct of our preclinical studies and clinical trials and for manufacturing and supply of our vaccine candidates. We have no internal manufacturing capabilities, and we will continue to rely on third parties, of which the main suppliers are single-source suppliers, for our preclinical and clinical trial materials. Given our stage of development, we do not yet have a marketing or sales organization or commercial infrastructure. Accordingly, if we obtain regulatory approval for any of our vaccine candidates, we also expect to incur significant commercialization expenses related to product sales, marketing, manufacturing and distribution.

Because of the numerous risks and uncertainties associated with vaccine development, we are unable to predict the timing or amount of increased expenses or when or if we will be able to achieve or maintain profitability. Even if we are able to generate revenue from the sale of our vaccines, we may not become profitable. If we fail to become profitable or are unable to sustain profitability on a continuing basis, then we may be unable to continue our operations at planned levels and may be forced to reduce our operations.

Certain Significant Relationships

We have entered into grant, license and collaboration arrangements with various third parties as summarized below. For further details regarding these and other agreements, see the section titled “Business — Intellectual Property” and Note 5 to each of our audited financial statements and unaudited financial statements included elsewhere in this prospectus.

Ology Agreement

In July 2019, we entered into a development and manufacturing master services agreement with Ology Bioservices (which was later acquired by National Resilience, Inc.) ("Ology"), which we refer to as the Ology Agreement, pursuant to which Ology is obligated to perform manufacturing process development and clinical manufacture and supply of components.

Under the Ology Agreement, we will pay Ology agreed upon fees for Ology's performance of manufacturing services, and we will reimburse Ology for its out-of-pocket costs associated with purchasing raw materials, plus a customary handling fee.

For additional details regarding our relationship with Ology, see the section entitled "Business — Manufacturing and Supply" and Note 5 to our financial statements included elsewhere in this prospectus.

Cincinnati Children's Hospital Medical Center Agreement

On June 1, 2021, we entered into an exclusive, worldwide license agreement with Children's Hospital Medical Center, d/b/a Cincinnati Children's Hospital Medical Center, or CHMC, which we refer to as the CHMC Agreement, pursuant to which we obtained the right to develop and commercialize certain CHMC patents and related technology directed at a virus-like particle (VLP) vaccine platform that utilizes nanoparticle delivery technology, which may have potential broad application to develop vaccines for multiple infectious diseases.

Under the CHMC Agreement, we agreed to pay CHMC certain license fees, deferred license fees, development milestone fees, and running royalties beginning on the first net sale (among others). For additional details regarding our relationship with CHMC, see the section entitled "Business — Intellectual Property — Exclusive License Agreement with Children's Hospital Medical Center, d/b/a Cincinnati Children's Hospital Medical Center" included elsewhere in this prospectus. The CHMC license includes:

U.S. Patent Application No.	U.S. Patent No.	Granted Claim Type	U.S. Expiration	Foreign Counterparts
12/797,396	8,486,421	Compositions of the vaccine/vaccine platform	1/13/2031	CN107043408B EP2440582B1 JP5894528B2
13/924,906	9,096,644	Method of treatment	9/20/2030	CN107043408B EP2440582B1 JP5894528B2
13/803,057	9,562,077	Compositions of the vaccine platform	4/10/2034	none
16/489,095	pending	pending**	[3/15/2038]*	Pending applications in Canada, China, EU and Japan
63/149,742 (filed 2/16/2021)	pending	pending**	[February 2042]#	TBD
63/162,369 (filed 3/17/2021)	pending	pending**	[March 2042]#	TBD

* Projected expiration if patent issues: 20 years from earliest non-provisional application filing date.

\# Non-provisional application not yet filed. Expiration projected 21 years from provisional application filing date. Dependent on timely conversion to non-provisional application and issuance of patent.

** This is a pending application. Claim type will be determined after U.S. prosecution is complete. The claim type sought includes compositions of the vaccine and vaccine platform.

Oxford University Innovation Limited Agreement

On July 16, 2019, we entered into an exclusive, worldwide license agreement with Oxford University Innovation Limited, which we refer to as the OUI Agreement, pursuant to which we obtained the right to develop and commercialize certain licensed technology entitled "Immunogenic Composition."

Under the OUI Agreement, we agreed to fund three years' worth of salaries for Dr. Craig Thompson in the University' Department of Zoology through a sponsored research agreement with Oxford University, as well as royalties on all net sales of licensed products, along with certain development and milestone payments (among others). For additional details regarding our relationship with OUI, see the section entitled "Business — Intellectual Property — License Agreement Between Oxford University Innovation Limited and Blue Water Vaccines, Inc." included elsewhere in this prospectus. The OUI license includes:

U.S. Patent Application No.	U.S. Patent No.	Granted Claim Type	U.S. Expiration	Foreign Counterparts
16/326,749	11,123,422	Compositions and method of treatment	8/25/2037	Pending applications in Australia, Canada, China, EU and Japan
17/458,712	pending	pending**	[8/25/2037]*	

* Projected expiration if patent issues: 20 years from earliest non-provisional application filing date.
** This is a pending application. Claim type will be determined after U.S. prosecution is complete. The claim type sought includes compositions of the compositions and method of treatment.

St. Jude Children's Research Hospital, Inc. Agreement

On January 27, 2020, we entered into an exclusive, worldwide license agreement with St. Jude Children's Research Hospital, Inc., which we refer to as the St. Jude Agreement, pursuant to which we acquired the right to develop certain licensed products and produce vaccines for use in humans.

Under the St. Jude Agreement, we agreed to pay an initial license fee, an annual maintenance fee, milestone payments, patent reimbursement, and running royalties based on the net sales of licensed products. For additional details regarding our relationship with St. Jude, see the section entitled "Business — Intellectual Property — Exclusive License Agreement between St. Jude Children's Research Hospital, Inc. & Blue Water Vaccines" included elsewhere in this prospectus. The St. Jude license includes:

U.S. Patent Application No.	U.S. Patent No.	Granted Claim Type	U.S. Expiration	Foreign Counterparts
14/345,988	9,265,819	Compositions and method of treatment	9/19/2032	none
17/602,414#	pending	pending**	[3/12/2040]*	Pending Applications in: Australia, Brazil, Canada, China, Europe, Hong Kong, Japan and Korea

* Projected expiration if patent issues: 20 years from earliest non-provisional application filing date.
# U.S. National stage entry of WO 2020/183420 (PCT/IB2020/052250).
** This is a pending application. Claim type will be determined after U.S. prosecution is complete. The claim type sought includes compositions of the compositions and method of treatment.

COVID-19 Impacts

We are continuing to closely monitor the impact of the global COVID-19 pandemic on our business and are taking proactive efforts designed to protect the health and safety of our employees and to maintain business continuity. We believe that the measures we are implementing are appropriate, and we will continue to monitor and seek to comply with guidance from governmental authorities and adjust our activities as appropriate. Based on guidance issued by federal, state and local authorities, we transitioned to a remote work model for a vast

majority of our employees in March 2020. The COVID-19 pandemic has resulted in an impact to our development timelines, as the pandemic continues, we could continue to see an impact on our ability to advance our programs, obtain supplies from our contract manufacturer or interact with regulators, ethics committees or other important agencies due to limitations in regulatory authority, employee resources or otherwise. In any event, if the COVID-19 pandemic continues and persists for an extended period of time, we could experience significant disruptions to our development timelines, which would adversely affect our business, financial condition, results of operations and growth prospects.

In addition, while the potential economic impact brought by, and the duration of, the COVID-19 pandemic may be difficult to assess or predict, the pandemic could result in significant and prolonged disruption of global financial markets, reducing our ability to access capital, which could in the future negatively affect our liquidity. In addition, a recession or market correction resulting from the spread of COVID-19 could materially affect our business and the potential value of our common stock.

The extent of the impact of the COVID-19 pandemic on our development and regulatory efforts, our ability to raise sufficient additional capital on acceptable terms, if at all, and the future value of and market for our common stock will depend on future developments that are highly uncertain and cannot be predicted with confidence at this time, such as the ultimate duration of the pandemic, travel restrictions, quarantines, social distancing and business closure requirements in the U.S. and in other countries, and the effectiveness of actions taken globally to contain and treat COVID-19. For additional information about risks and uncertainties related to the COVID-19 pandemic that may impact our business, financial condition and results of operations, see the section titled “Risk Factors.”

Components of Results of Operations

Research and Development Expenses

Substantially all of our research and development expenses consist of expenses incurred in connection with the development of our product candidates. These expenses include fees paid to third parties to conduct certain research and development activities on our behalf, consulting costs, costs for laboratory supplies, product acquisition and license costs, certain payroll and personnel-related expenses, including salaries and bonuses, employee benefit costs and stock-based compensation expenses for our research and product development employees and allocated overheads, including information technology costs and utilities and expenses for the issuance of shares pursuant to the anti-dilution clause in the purchase of in process research and development technology. We expense both internal and external research and development expenses as they are incurred.

We do not allocate our costs by product candidate, as a significant amount of research and development expenses include internal costs, such as payroll and other personnel expenses, laboratory supplies and allocated overhead, and external costs, such as fees paid to third parties to conduct research and development activities on our behalf, are not tracked by product candidate.

We expect our research and development expenses to increase substantially for at least the next few years, as we seek to initiate additional clinical trials for our product candidates, complete our clinical programs, pursue regulatory approval of our product candidates and prepare for the possible commercialization of such product candidates. Predicting the timing or cost to complete our clinical programs or validation of our commercial manufacturing and supply processes is difficult and delays may occur because of many factors, including factors outside of our control. For example, if the FDA or other regulatory authorities were to require us to conduct clinical trials beyond those that we currently anticipate, we could be required to expend significant additional financial resources and time on the completion of clinical development. Furthermore, we are unable to predict when or if our product candidates will receive regulatory approval with any certainty.

General and Administrative Expenses

General and administrative expenses consist principally of payroll and personnel expenses, including salaries and bonuses, benefits and stock-based compensation expenses, professional fees for legal, consulting, accounting and tax services, including information technology costs, and other general operating expenses not otherwise classified as research and development expenses.

We anticipate that our general and administrative expenses will increase as a result of increased personnel costs, expanded infrastructure and higher consulting, legal and accounting services costs associated with complying with the applicable stock exchange and the SEC requirements, investor relations costs and director and officer insurance premiums associated with being a public company.

Other Income

Other income consists primarily of interest income.

Results of Operations

Comparison of Six Months ended June, 2021 and 2020

The following table summarizes our statements of operations for the six months ended June 30, 2021 and 2020:

	Six months ended June 30, 2021	Six months ended June 30, 2020	$ Change	% Change
	(Unaudited)	(Unaudited)		
Operating costs and expenses				
General and administrative	$ 500,276	$ 559,775	(59,499)	(10.6)%
Research and development	617,779	320,336	297,443	92.9%
Total operating expenses	1,118,055	880,111	237,944	27.0%
Loss from operations	(1,118,055)	(880,111)	(237,944)	27.0%
Other income				
Interest income	—	19,431	(19,431)	(100.0)%
Total other income	—	19,431	(19,431)	(100.0)%
Net Loss	$ (1,118,055)	$ (860,680)	(257,375)	29.9%

Operating Expenses

Research and Development Expenses

During the six months ended June 30, 2021, research and development expenses increased by approximately $0.3 million compared to the comparable prior year period. The increase was primarily attributable to an increase in licensing fees.

General and Administrative Expenses

During the six months ended June 30, 2021, general and administrative expenses decreased by approximately $60,000 compared to the comparable prior year period. The decrease was mainly due to decrease in stock-based compensation expenses of approximately $159,000, offset partially by an increase of professional and outside service fees of approximately $70,000.

Other Income

During the six months ended June 30, 2021, other income decreased by approximately $19,000 compared to the corresponding period in 2020. The decrease was primarily due to decrease in interest income after transitioning our bank account from a money market account to a business checking account.

Comparison of the Years Ended December 31, 2020 and 2019

The following table summarizes our statements of operations and comprehensive loss for the periods indicated:

	Year Ended December 31, 2020	Year Ended December 31, 2019	$ Change	% Change
Operating costs and expenses				
General and administrative	$ 1,097,161	$ 820,058	277,103	33.8%
Research and development	524,908	60,174	464,734	772.3%
Total operating expenses	1,622,069	880,232	741,837	84.3%
Loss from operations	(1,622,069)	(880,232)	(741,837)	84.3%
Other income				
Interest income	22,603	58,317	(35,714)	(61.2)%
Total other income	22,603	58,317	(35,714)	(61.2)%
Net loss	$ (1,599,466)	$ (821,915)	(777,551)	94.6%

Research and Development Expenses

For the year ended December 31, 2020, research and development expenses increased by approximately $0.5 million compared to 2019. The increase was primarily attributable to an increase in research contract expenses mainly related to our lead vaccine candidates, BWV-101 and BWV-102, of approximately $0.2 million, stock-based compensation expenses of approximately $0.2 million and licensing fees of approximately $0.1 million.

General and Administrative Expenses

For the year ended December 31, 2020, general and administrative expenses increased by $0.3 million compared to 2019. The increase was primarily attributable to an increase in personnel-related costs of approximately $0.2 million, and stock-based compensation expenses of $0.1 million.

Other Income

For the year ended December 31, 2020, other income decreased by $36,000 compared to 2019. The decrease was primarily due to decrease in interest income after transitioning our bank account from a money market account to a business checking account.

Going Concern, Liquidity and Capital Resources

Going Concern

There is substantial doubt about our ability to continue as a going concern for one year after the date that our June 30, 2021 financial statements are available to be issued, which is not alleviated by our plans. The financial statements do not reflect any adjustments relating to the recoverability and reclassification of assets and liabilities that might be necessary from the outcome of this uncertainty.

Since inception, we have devoted substantially all of our efforts to research and development, undertaking preclinical studies and enabling manufacturing activities in support of our product development efforts, hiring personnel, acquiring 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. We do not have any products approved for sale and have not generated any revenue from product sales. We have incurred net losses in each year since inception and expect to continue to incur net losses in the foreseeable future. Our net loss was $1.6 million for the year ended December 31, 2020. As of December 31, 2020, we had an accumulated deficit of $2.5 million. We also generated negative operating cash flows of $1.7 million for the year ended December 31, 2020.

For the six months ended June 30, 2021, our net loss was $1.1 million and we used $0.6 million of cash in operations. As of June 30, 2021, we had an accumulated deficit of $3.7 million. Our cash is sufficient to continue operations, satisfy its obligations and fund the future expenditures that will be required to conduct the clinical and regulatory work to develop its product candidates until the second quarter of 2022.

Liquidity and Capital Resources

We have incurred losses since inception and have incurred negative cash flows from operations from inception through June 30, 2021. We have funded our operations to date primarily from the sale of preferred securities to seed investors totaling approximately $6.9 million in net proceeds. As of June 30, 2021, we had $3.7 million of cash and an accumulated deficit of $3.7 million.

We will require significant amounts of additional capital to continue to fund our operations and commence and complete our research and development activities. We currently have limited resources to continue to fund our operations and if we are not able to obtain additional cash resources, we will not be able to continue operations. We will continue seeking additional financing sources to meet our working capital requirements, make continued investment in research and development and make capital expenditures needed for us to maintain and expand our business. We may not be able to obtain additional financing on terms favorable to us, if at all. If we are unable to obtain adequate financing or financing on terms satisfactory to us when we require it, or if we expend capital on projects that are not successful, our ability to continue to support our business growth and to respond to business challenges could be significantly limited, or we may even have to cease our operations. If we raise additional funds through further issuances of equity or convertible debt securities, our existing stockholders could suffer significant dilution, and any new equity securities we issue could have rights, preferences and privileges superior to those of holders of our common stock, including shares of common stock sold in this offering.

Future Funding Requirements

Our primary uses of cash are to fund our operations, which consist primarily of research and development expenditures related to our programs and general and administrative expenditures. We anticipate that we will continue to incur significant expenses for the foreseeable future as we continue to advance our vaccine candidates, expand our corporate infrastructure, including the costs associated with being a public company and further our research and development initiatives for our vaccine candidates. We are subject to all of the risks typically related to the development of new drug candidates, and we may encounter unforeseen expenses, difficulties, complications, delays and other unknown factors that may adversely affect our business. We anticipate that we will need substantial additional funding in connection with our continuing operations.

We believe that our existing cash as of the date of this prospectus, together with the net proceeds from this offering, will fund our current operating plans through at least the next 12 months from the date of this offering. However, we will need to raise additional capital prior to commencing pivotal trials for any of our vaccine candidates. Until we can generate a sufficient amount of revenue from the commercialization of our vaccine candidates or from collaboration agreements with third parties, if ever, we expect to finance our future 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. The future sale of equity or convertible debt securities may result in dilution to our stockholders and, in the case of preferred equity securities or convertible debt, those securities could provide for rights, preferences or privileges senior to those of our common stock. Debt financings may subject us to covenant limitations or restrictions on our ability to take specific actions, such as incurring additional debt, making capital expenditures or declaring dividends. Our ability to raise additional funds may be adversely impacted by deteriorating global economic conditions and the recent disruptions to and volatility in the credit and financial markets in the United States and worldwide resulting from the ongoing COVID-19 pandemic. There can be no assurance that we will be successful in acquiring additional funding at levels sufficient to fund our operations or on terms favorable or acceptable to us. If we are unable to obtain adequate financing when needed or on terms favorable or acceptable to us, we may be forced to delay, reduce the scope of or eliminate one or more of our research and development programs.

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 and non-clinical studies and clinical trials, including any impacts related to the COVID-19 pandemic;
- 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 our patents or other intellectual property rights;
- 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, which may exacerbate the magnitude of the factors discussed above.

A change in the outcome of any of these or other variables could significantly change the costs and timing associated with the development of our vaccine candidates. Furthermore, our operating plans may change in the future, and we may need additional funds to meet operational needs and capital requirements associated with such change.

Cash Flows

The following table summarizes our cash flows for the periods indicated:

	Six months ended June 30, 2021	Six months ended June 30, 2020	Year Ended December 31, 2020	Year Ended December 31, 2019
	(Unaudited)	(Unaudited)		
Net cash used in operating activities	(639,353)	(1,252,208)	(1,730,138)	(825,126)
Net cash used in investing activities	—	(6,027)	(11,792)	(4,500)
Net cash provided by financing activities	—	—	—	6,880,377
Net (decrease) increase in cash	(639,353)	(1,258,235)	(1,741,930)	6,050,751

Cash Flows from Operating Activities

Net cash used in operating activities for the six months ended June 30, 2021 was $0.6 million, which primarily resulted from a net loss of $1.1 million, and partially offset by a net change in our operating assets and liabilities of $0.4 million and stock-based compensation of $77,000.

Net cash used in operating activities for the six months ended June 30, 2020 was $1.3 million, which primarily resulted from a net loss of $0.9 million and a net change in our operating assets and liabilities of $0.6 million, partially offset by stock-based compensation of $0.2 million.

Net cash used in operating activities for the year ended December 31, 2020 was $1.7 million, which primarily resulted from a net loss of $1.6 million and a net change in our operating assets and liabilities of $0.5 million, partially offset by stock-based compensation of $0.3 million.

Net cash used in operating activities for the year ended December 31, 2019 was $0.8 million, which primarily resulted from a net loss of $0.8 million.

Cash Flows from Investing Activities

Net cash used in investing activities for the six months ended June 30, 2021 was $0.

Net cash used in investing activities for the six months ended June 30, 2020 was $6,000, which resulted from purchase of property and equipment.

Net cash used in investing activities for the year ended December 31, 2020 was $12,000, which resulted from purchase of property and equipment.

Net cash used in investing activities for the year ended December 31, 2019 was $5,000, which resulted from purchase of property and equipment.

Cash Flows from Financing Activities

Net cash used in financing activities for the six months ended June 30, 2021 and 2020, and for the year ended December 31, 2020 was $0.

Cash provided by financing activities for the year ended December 31, 2019 was $6.9 million, which primarily consisted of net proceeds from the issuance of our Series Seed preferred stock of $6.9 million, partially offset by repayment of related party loan of $55,000.

Legal Contingencies

From time to time, we may become involved in legal proceedings arising from the ordinary course of business. We record a liability for such matters when it is probable that future losses will be incurred and that such losses can be reasonably estimated.

Off-Balance Sheet Arrangements

During the periods presented we did not have, nor do we currently have, any off-balance sheet arrangements as defined in the rules and regulations of the SEC.

Recent Accounting Pronouncements Not Yet Adopted

See Note 3 to our financial statements included elsewhere in this prospectus for more information.

Critical Accounting Policies and Estimates

Our financial statements have been prepared in accordance with U.S. generally accepted accounting principles (“U.S. GAAP”). The preparation of these financial statements requires us to make estimates and judgments that affect the reported amounts of assets, liabilities, and expenses and the disclosure of contingent assets and liabilities in our financial statements. On an ongoing basis, we evaluate our estimates and judgments, including those related

to accrued research and development expenses fair value of common stock and stock-based compensation. We base our estimates on historical experience, known trends and events and various other factors that are believed to be reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources. Actual results may differ from these estimates under different assumptions or conditions.

While our significant accounting policies are described in more detail in Note 3 to our financial statements included elsewhere in this prospectus, we believe the following accounting policies and estimates to be most critical to the judgments and estimates used in the preparation of our financial statements.

Accrued Research and Development Expenses

We have entered into various agreements with contract manufacturing organizations, or CMOs, and may enter into contracts with clinical research organizations, or CROs, in the future. As part of the process of preparing our financial statements, we are required to estimate our accrued research and development expenses as of each balance sheet date. This process involves reviewing open contracts and purchase orders, communicating with our personnel and third parties to identify services that have been performed on our behalf and estimating the level of service performed and the associated cost incurred for the service when we have not yet been invoiced or otherwise notified of the actual cost. We make estimates of our accrued research and development expenses as of each balance sheet date based on facts and circumstances known to us at that time. We periodically confirm the accuracy of our estimates with the service providers and make adjustments, if necessary. The significant estimates in our accrued research and development expenses include the costs incurred for services performed by our vendors in connection with research and development activities for which we have not yet been invoiced.

We accrue for costs related to research and development activities based on our estimates of the services received and efforts expended pursuant to quotes and contracts with vendors, including CMOs, that conduct research and development on our behalf. The financial terms of these agreements are subject to negotiation, vary from contract to contract and may result in uneven payment flows. There may be instances in which payments made to our vendors will exceed the level of services provided and result in a prepayment of the research and development expense. Advance payments for goods and services that will be used in future research and development activities are expensed when the activity has been performed or when the goods have been received. We make significant judgments and estimates in determining accrued research and development liabilities as of each reporting period based on the estimated time period over which services will be performed and the level of effort to be expended. If the actual timing of the performance of services or the level of effort varies from our estimate, we adjust the accrual or prepaid expense accordingly.

Although we do not expect our estimates to be materially different from amounts actually incurred, if our estimates of the status and timing of services performed differ from the actual status and timing of services performed, it could result in us reporting amounts that are too high or too low in any particular period. To date, there have been no material differences between our estimates of such expenses and the amounts actually incurred.

Stock-Based Compensation

The Company expensed stock-based compensation to employees and non-employees over the requisite service period based on the estimated grant-date fair value of the awards. Stock-based awards to employees with graded-vesting schedules are recognized, using the accelerated attribution method, on a straight-line basis over the requisite service period for each separately vesting portion of the award. Changes in the estimated fair value of awards are recognized as compensation expense in the period of change.

The Company estimates the fair value of stock option grants using the Black-Scholes option pricing model and the assumptions used in calculating the fair value of stock-based awards represent management's best estimates and involve inherent uncertainties and the application of management's judgment.

Expected Term — The expected term of options represents the period that the Company's stock-based awards are expected to be outstanding based on the simplified method, which is the half-life from vesting to the end of its contractual term.

Expected Volatility — The Company computes stock price volatility over expected terms based on comparable companies historical common stock trading prices.

Common Stock Fair Value — The fair value of the common stock underlying the Company's stock options was estimated at each grant date and was determined with the assistance of an independent third-party valuation expert. The assumptions underlying these valuations represented management's best estimates, which involved inherent uncertainties and the application of significant levels of management judgment.

Risk-Free Interest Rate — The Company bases the risk-free interest rate on the implied yield available on U.S. Treasury securities with a remaining term commensurate with the estimated expected term.

Expected Dividend — The Company has never declared or paid any cash dividends on its common shares and does not plan to pay cash dividends in the foreseeable future, and, therefore, uses an expected dividend yield of zero in its valuation models.

The Company recognizes forfeitures of equity awards as they occur.

Fair value of common stock

In order to determine the fair value of shares of common stock of the Company when issuing stock options and computing their estimated stock-based compensation expense, its board of directors considered with input from third party valuations, among other things, contemporaneous valuations of the Company's common stock. Given the absence of a public trading market of the Company's capital stock to date, its board of directors has exercised reasonable judgment and considered a number of objective and subjective factors to determine the best estimate of the fair value of our common and preferred stock, including:

- the prices, rights, preferences and privileges of our preferred stock relative to our common stock;
- our business, financial condition and results of operations, including related industry trends affecting our operations;
- the likelihood of achieving a liquidity event, such as an initial public offering, or IPO, or sale of our company, given prevailing market conditions;
- the lack of marketability of our common stock;
- the market performance of comparable publicly traded companies;
- U.S. and global economic and capital market conditions and outlook; and
- Common stock valuation methodology.

In estimating the fair market value of common stock of the Company, its board of directors first determined the equity value of its business using accepted valuation methods.

The Company engaged a third party valuation specialist to conduct a valuation, which used its recent preferred stock financing as a starting point and determined the equity value of the company based on the Backsolve method using an Option Pricing Method (OPM) to calculate the implied value based on a market approach. The Company's equity value was allocated using OPM to estimate the fair market value of the Company's classes of equity.

Quantitative and Qualitative Disclosures About Market Risk

We are a smaller reporting company as defined by Rule 12b-2 of the Exchange Act and are not required to provide the information otherwise required under this item.

JOBS Act

Section 107 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. In other words, an "emerging growth company" can delay the adoption of new or revised accounting standards until those standards would otherwise apply to private companies. We have elected to avail ourselves of this extended transition period.

For as long as we remain an "emerging growth company" under the recently enacted JOBS Act, we will, among other things:

- be exempt from the provisions of Section 404(b) of the Sarbanes-Oxley Act, which requires that our independent registered public accounting firm provide an attestation report on the effectiveness of our internal control over financial reporting;
- be permitted to omit the detailed compensation discussion and analysis from proxy statements and reports filed under the Exchange Act and instead provide a reduced level of disclosure concerning executive compensation; and
- be exempt from any rules that may be adopted by the Public Company Accounting Oversight Board requiring mandatory audit firm rotation or a supplement to the auditor's report on the financial statements.

Although we are still evaluating the JOBS Act, we currently intend to take advantage of some or all of the reduced regulatory and reporting requirements that will be available to us so long as we qualify as an "emerging growth company," including the extension of time to comply with new or revised financial accounting standards available under Section 102(b) of the JOBS Act. Among other things, this means that our independent registered public accounting firm will not be required to provide an attestation report on the effectiveness of our internal control over financial reporting so long as we qualify as an emerging growth company, which may increase the risk that weaknesses or deficiencies in our internal control over financial reporting go undetected. Likewise, so long as we qualify as an emerging growth company, we may elect not to provide you with certain information, including certain financial information and certain information regarding compensation of our executive officers, that we would otherwise have been required to provide in filings we make with the SEC, which may make it more difficult for investors and securities analysts to evaluate our company. As a result, investor confidence in our company and the market price of our common stock may be materially and adversely affected.

BUSINESS

Overview

We are a biotechnology company focused on the research and development of transformational vaccines to prevent infectious diseases worldwide. Our versatile vaccine platform has unique molecular properties that enables delivery of various antigens, which can be utilized to develop singular or multi-targeted vaccines. Our lead influenza (flu) vaccine program uses proprietary technology to identify specific epitopes, or proteins, with cross-reactive properties that enables the potential development of a universal flu vaccine. We are focused on developing novel vaccines that induce durable and long-term immunity. 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.

Our pipeline includes novel vaccine candidates exclusively licensed from renowned research institutions. 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 exclusive license agreements include patented influenza epitopes of limited variability, or ELV, identified through a proprietary computational research and discovery process, discovered by Dr. Sunetra Gupta and her team at the University of Oxford. Our collaborators are pioneers in vaccine discovery and development. We are exploring the development of these influenza ELV's 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 our platform to develop a vaccine for the prevention of gastroenteritis cause by both norovirus and rotavirus. Our exclusively licensed S. pneumoniae vaccine candidate is from St. Jude Children's Research Hospital. The vaccine is designed to prevent harmful middle-ear infections in children and is being developed for intranasal delivery well suited for pediatric patients. We leverage the expertise of our collaborators to pursue the discovery and development of vaccines for these diseases, which are 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.

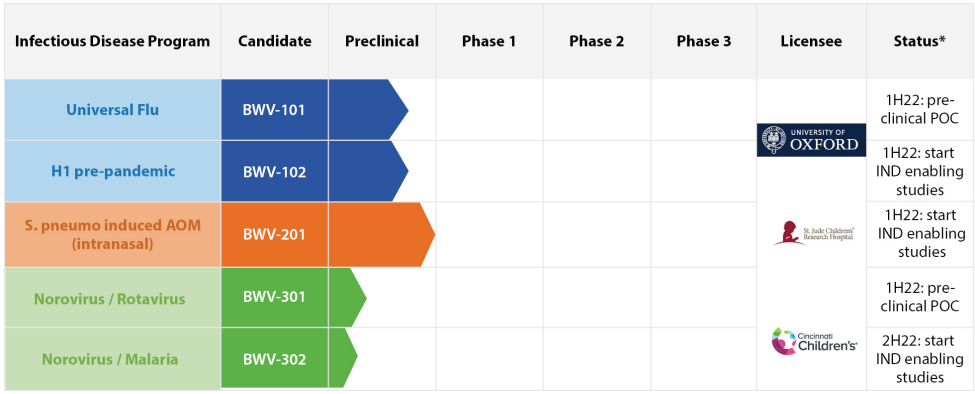
This market acceleration has been coupled with various strategic transactions in the sector, including consolidations and mergers and acquisitions in recent years. Major market participants have strategically acquired start-ups and mid-sized companies to broaden their products portfolios and service 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. 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, or CDC, its Advisory Committee on Immunization Practices, or 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.



Strategy

We aim to identify, discover and develop novel preventive vaccines for infectious diseases. Key elements of our strategy include:

- **Investment in advancing the development of our novel vaccine pipeline programs through IND-enabling activities and Phase I clinical studies.**
  - We plan to advance our main vaccine programs: influenza, *S. pneumoniae* induced AOM norovirus-rotavirus, and norovirus-malaria.
  - Our in-licensed vaccine candidates are carefully selected based on the following criteria: area of significant unmet medical need for preventive long-term vaccine; strong scientific rationale and established clinical and regulatory pathways; defined competitive landscape and potential future commercial opportunity; and license exclusivity.
- **Prioritizing the research and development for our lead influenza vaccine candidates, BWV-101 and BWV-102 through Phase I.**
  - Our goal is to develop a universal influenza vaccine that protects against all strains of influenza, including pandemic strains. In collaboration with The University of Oxford and CHMC, we are evaluating vaccine candidates to pursue the best development path forward to stimulate durable and broad-spectrum immunogenicity.
  - We will leverage the pre-clinical and clinical experience we gain from the development of BWV-102 to accelerate the development of the BWV-101 program. We expect that the manufacturing and clinical data collected will provide invaluable insight for development of the universal vaccine candidate.

- **Maximize and utilize the value of our collaborators and third-party vendors.**
  - We will combine disciplined business strategies to further expand the potential synergies with current collaborators.
- **Deploy and expand our proprietary norovirus S&P nanoparticle platform.**
  - Our immunogenic multi-purpose vaccine platform technologies can be utilized with an array of infectious disease agents to access multiple development pathways and allow for potential next-generation life cycle management to expand our pipeline and pursue business development opportunities. There is potential for the platform to pursue adjunctive therapies to currently available drugs, and for current therapies to be re-optimized and formulated to protect against multiple antigens.

Management and History

Blue Water Vaccines, Inc. was founded in October 2018 by our Chief Executive Officer, or CEO, Joseph Hernandez, with the initial goal of developing a transformational universal flu vaccine to treat and prevent infections in patients globally. Our initial technology, licensed from the University of Oxford, provides a novel approach to developing a universal influenza vaccine. Subsequently, our team has identified other program candidates and technologies to broaden and diversify our vaccine pipeline.

Mr. Hernandez, our Chairman and CEO, is a veteran entrepreneur, philanthropist, and operator with a broad skillset of founding, building, and selling companies, as well as executing business development transactions and securing private and public capital, including Digene, Noachis Terra and Blue Water Acquisition Corp. Mr. Hernandez was responsible for our initial $7 million seed funding round from investors including CincyTech. In addition to his position as our Chairman and CEO, Mr. Hernandez also serves as the chairman of the board of directors for Clarus Theraputics, Inc. (Nasdaq: CRXT) in addition to certain other private companies. Subsequently, a team of veteran industry executives and advisors were assembled, bringing valuable expertise to our growing infectious disease company.

Jon Garfield, our Chief Financial Officer upon the consummation of this offering, has over 20 years of financial leadership experience, including with healthcare companies. Mr. Garfield regularly provides consulting services to private equity funds and privately held companies and has served as the CEO of Unity MSK since February 2021, and he has served as Chief Financial Officer of Blue Water Vaccines, Inc. since September 2021. Erin Henderson, who serves as our Chief Business Officer, has over 20 years of leading strategic transactions, governmental and stakeholder relations and corporate expansion. Previously, since 2010 she was the Managing Principal at The Aetos Group, a management consulting firm serving both the public and private sectors. Andrew Skibo is our Head of Biologic Operations and was recently Head of Global Biologics Operations at MedImmune/AstraZeneca and previously worked for Amgen and Genentech (now Roche), where he was responsible for operations, engineering, construction, and validation for large-scale capital projects related to bio-pharmaceutical manufacturing. Ronald Cobb, Ph.D., our Head of Science and Discovery, was recently Chief Scientific Officer at Ology Bioservices (formerly Nanotherapeutics) and previously worked for RTI Biologics and Berlex Biosciences. Brian Price, Ph.D., our Head of Technology Strategy, brings over 20 years of successful product development experience and business development growth based on programs in toxicology, analytics, and therapeutic and vaccine development.

Additionally, members of our Board of Directors have extensive expertise in the fields of life sciences, business, and finance. In addition to Mr. Hernandez, our directors upon the consummation of this offering include Michael Venerable, CEO of CincyTech, Kimberly Murphy, former VP, Commercialization Leader, influenza at GlaxoSmithKlein, Allan Shaw, an experienced biotechnology CFO and director nominee James Sapirstein, R.Ph., M.B.A, President and CEO of AzurRx BioPharma (Nasdaq:AZRX). Our Scientific Advisory Board includes Sunetra Gupta, Ph.D. Professor of Theoretical Epidemiology at The University of Oxford, a leading voice in infectious disease globally; David Zarley, Ph.D., with more than 30 years of experience in vaccine research and development, including former leadership roles at Pfizer and Wyeth; and, following the consummation of this offering, John Rice, Ph.D., Managing Director at CincyTech, with more than 30 years of biotechnology advising experience.

Subject to certain non-compete restrictions, our chief executive officer, Joseph Hernandez, and other key personnel may pursue other business or investment ventures while employed with us. Accordingly, they may have conflicts of interest in allocating time among various business activities and potentially competitive fiduciary and pecuniary interests that conflict with our interests. See “Risk Factors — Our Chief Executive Officer, Joseph

Hernandez and our Chief Financial Officer, Jon Garfield, hold certain management positions and directorships of other companies and may allocate their time to such other businesses, which may cause conflicts of interest in their determination as to how much time to devote to our affairs and potentially competitive fiduciary and pecuniary interests that conflict with our interests." For a complete discussion of the business affairs of our officers, directors and other personnel, please see "Management — Executive Officers and Directors." Any such additional business activities or ventures may present conflicts to our interests. We do not believe that any such potential conflicts would materially affect our ability to conduct our operations.

Our Vaccine Platform

BWV Norovirus (NoV) S&P Nanoparticle Versatile Vaccine Platform

Bioengineering the shell (S) and protruding (P) domains of the norovirus capsid protein, polyvalent nanoparticles and polymers/oligomers provide a versatile vaccine platform with wide applications

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).

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.

Viral capsid proteins are responsible for many basic functions necessary for viral life cycles, such as viral attachment and entry, and thus can elicit neutralizing antibodies against viral infection after immunization to humans and animals. Consequently, viral capsid proteins are promising vaccine targets against viral infection. Indeed, various capsid protein nanoparticles and complexes have been developed and used as nonreplicating subunit vaccines to combat various infectious diseases.

Unlike traditional live-attenuated and inactivated virus vaccines that need cultivation of infectious virions and are associated with certain safety concerns, the nonreplicating VLP vaccines derived from bioengineered viral capsid proteins do not involve an infectious agent and, therefore, may be safer and have lower manufacturing costs than traditional vaccines. Thus, VLP vaccines represent a next generation of innovative vaccine strategy.

Structure

- The NoV (VP1) capsid structure consists of two major domains a N-terminal shell (S) and C-terminal protruding (P) domains. The S domain builds the interior shell of the capsid and the P domain forms the dimeric protrusions of the capsid.
- The protrusions (P) of norovirus capsid interact with viral glycan receptors for attachment to host cells to initiate an infection.
- The S domain interacts homotypically and drives self-formation of an approximately 60 nm VLP.
- The P domain exhibits homotypic interactions, forming a 24 nm VLP with dimeric protrusions for stabilization of the viral capsid. Additionally, it can also form oliogomers or polymers.

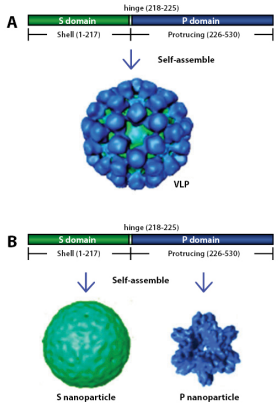


Figure 1. Lineage structures of norovirus capsid protein or viral protein 1 (VP1) and various nanoparticles derived from full-length or truncated VP1. The N-terminal shell (S) (green) and the C-terminal protruding (P) (dark blue) domains with a short flexible hinge (light blue) in between (with amino acid numbers based on GI.1 Norwalk virus VP1) are shown. (A) Production of full-length norovirus VP1s via a eukaryotic expression system self-assembles into virus-like particles (VLPs).(B) Production of the S or P domain via the *Escherichia coli* expression system self-assembles into S or P nanoparticles.

Due to the homotypic interaction attributed to the norovirus capsid domains, researchers at CHMC, through bioengineering, designed and generated two subviral nanoparticles, the 24-valent P_{24} and the 60-valent S_{60} nanoparticles, and P-derived polymers to serve as a multifunctional vaccine platform against different pathogens and illnesses.

- These nanoparticles and polymers are easily produced, highly stable, and extremely immunogenic which we believe makes them compelling platforms to serve to display foreign antigens, self-assembling into chimeric nanoparticles or polymers as vaccine candidates.
- There are several preclinical studies that showed P_{24}/S_{60} chimeric vaccine candidates that can display different foreign antigens and epitopes, as set forth below in Tables 1 and 2. Therefore, there may be additional candidates to further explore as human vaccines. *(Xia et al. ACS Nano 2018, 12, 10665−10682).*
- Such VLPs and capsid-like nanoparticles may be excellent vaccine candidates against corresponding viral pathogens because they can retain arrays of antigenic epitopes that faithfully mimic those of the native virions, and these repeated viral antigens and epitopes stimulate strong immune responses in their animal and human hosts. In addition, such highly immunogenic subviral nanoparticles may also serve as versatile platforms that are able to display foreign antigens for improved immune responses to facilitate development of novel vaccines against various pathogens and diseases.

- The fact that the P_{24} VLP nanoparticles and polymers are composed of authentic norovirus antigens and retain norovirus-specific molecular patterns make it an excellent vaccine candidate against the norovirus.
- In addition, the natures of self-formation, high stability, polyvalence, and high immunogenicity, as evidenced by animal studies conducted in gnotobiotic pig models and mouse models, results included herein, of the nanoparticles and polymers make them strong vaccine candidate platforms to display foreign antigens, resulting in chimeric nanoparticles as vaccine candidates against further pathogens and diseases.

Our multifunctional vaccine platform is a robust discovery engine and has broad application using both S_{60} and P_{24} nanoparticles to target multiple pathogens and illnesses.

The P_{24} nanoparticle has also been used to display multiple viral epitopes for enhanced immunogenicity for novel subunit vaccine development, see Table 1 below. These include the M2e epitope of the matrix 2 (M2) protein and the HA2 protein B cell epitope of influenza viruses, the B cell epitope of VP3 of enterovirus 71 (EV71), the 4E10 and 10E8 epitopes of human immunodeficiency virus type 1 (HIV-1), among others.

Table 1. Summary of norovirus nanoparticles and polymers as vaccine candidates and platforms to display foreign antigens and epitopes.

Nanoparticle/ Polymer	Antigen/Epitope to be Displayed (Pathogen)	Chimeric Products as Vaccine Candidate	Immunity against Pathogens or Diseases
S_{60}	VP8* (rotavirus)	S_{60}–VP8*	Rotavirus
P_{24}	P domain (norovirus)	P_{24}	Norovirus
P_{24}	VP8* (rotavirus)	P_{24}–VP8*	Rotavirus and norovirus
P_{24}	M2e (influenza virus)	P_{24}–M2e	Influenza virus
P_{24}	HA2 B cell epitope (influenza virus)	Trivalent HA2-PP (P_{24}-HA2:90-105)	Influenza A virus and influenza B virus
P_{24}	VP3 B cell epitope (EV71)	PP-71-6 (P_{24}-71-6)	EV71
P_{24}	4E10/10E8 epitopes (HIV-1)	4E10-PP/10E8-PP	HIV-1
P_{24}	Amyloid-beta, Aβ	PP-3copy-Aβ1-6	Alzheimer's disease
P polymer	P domains (noroviruses)	NoV P_{GI}-NoV P_{GII} GST NoV P^{+}	Different noroviruses
P polymer	P domain (HEV)	NoV P-HEV P	Norovirus and HEV
P polymer	P domain (astrovirus) P domain (HEV)	Ast P-HEV P-NoV P	Norovirus, astrovirus, and HEV
P polymer	P domain (astrovirus) P domain (HEV) VP8* (rotavirus)	Ast P-HEV P-VP8*	Rotavirus, astrovirus, and HEV

Note: EV71, enterovirus 71; HIV-1, human immunodeficiency virus type 1; HEV, hepatitis E virus; Ast, astrovirus,NoV, norovirus, P, protruding domain; P+, the P domain with an end-linked cysteine-containing peptide that canself-assemble into oligomers; PP, P particle; GI, norovirus genogroup I; GII, norovirus genogroup II. Please see themain text for details.

The S_{60} Nanoparticle as a Multifunctional vaccine platform

Recent technology has generated S nanoparticles using an *E. coli* system with stabilized expression and self-assembly. The S nanoparticles feature exposed C-terminal flexible hinge sites that offer ideal fusion sites for displaying foreign antigens.

Researchers at CHMC have developed a technology to produce uniform 60-valent NoV S_{60} nanoparticles with high efficiency using a simple bacterial expression system. This was achieved by taking advantage of the homotypic interactions of the NoVVP1 S domain that naturally builds the interior shells of NoV capsids, as well as several modifications to stabilize the S domain proteins and enhance the inter-S domain interactions, respectively.

Specifically, we introduced an R69A mutation to destruct the exposed protease cleavage sites on the surface of the native shell that otherwise leads to easy degradation of the S proteins. In addition, we introduced triple (V57C/Q58C/S136'C) cysteine mutations to establish inter-S domain disulfide bonds between two pairs of sterically close residues that belong to two neighboring S domains. This led to significantly enhanced stability and yields of the self-assembled S_{60} nanoparticles produced by the simple *E. coli* system. The below bullets are supported by published data by Ming Xia, the co-inventor of the S&P platform, and his research team at CHMC.

- An important feature of our technology was to rationally introduce intermolecular disulfide bonds to stabilize the S_{60} nanoparticles. This approach could also be used to stabilize other viral protein particles or complexes.
- The 60 freely exposed C-termini are a key feature facilitating the S_{60} nanoparticle to be a useful vaccine platform. Foreign antigens or epitopes can simply be fused to the end of the S domain via flexible linker through recombinant DNA technology.
- Uniform 60-valent NoV VLPs or S particles produced in a bacterial expression system have not been produced before.
- Importantly, our S_{60} nanoparticles maintained the native conformation with authentic antigenicity; thus, our NoV S_{60} nanoparticle technology represents a significant bioengineering advancement as uniform 60-valent NoV VLP or S particle *via* an expression system have never been produced before (Xia et al. ACS Nano 2018, 12, 10665−10682).
- Uniform complexity and size of vaccine particles are important factors in quality control of vaccine products, as variations in complexity and size will result in variations in immunization outcomes of the vaccines.

Broad application to fuse several antigens to the S_{60} nanoparticle based on multiple studies shown below conducted by CHMC (Xia et al. ACS Nano 2018, 12, 10665−10682)

CHMC has been able to fuse several antigens to the S_{60} nanoparticle to the same exposed S domain C-terminus via the same linker. These included (1) the rotavirus (RV) surface spike protein VP8*; (2) the HA1 antigen or receptor-binding domain (RBD) (223 amino acids) of the hemagglutinin (HA) of anH7N9 influenza A virus; (2) the TSR antigen (67 amino acids) of the circumsporozoite surface protein (CSP) of the malaria parasite Plasmodium falciparum; (3) the protruding domain antigen (187 amino acids) of a hepatitis E virus; (4) a longer version of the RV VP8*antigen (231 amino acids); and (5) the VP8*antigen (159 amino acids) of the murine RV (mRV) EDIM strain (Table 1). Particle formations of these fusion proteins have been shown by gel-filtration and/or EM (Table1). In addition, they have shown that the S_{60}nanoparticle-displayed HA1 and mRV VP8*antigens elicited significantly higher HA1- and mRV VP8*-specific antibody titers, respectively, than those elicited by the free HA1 or mRV VP8*antigens (Table 2).

Table 2. List of Antigens That Have Been Displayed by the S_{60} Nanoparticles

epitope/ antigen	size (residue)	yield (mg/L bacteria culture)	S_{60} antigen particle formation	significant immune enhancement in mice[f]
RV VP8* antigen	159	~40	yes	yes
HA1 antigen[a]	223	~10	yes	yes
TSR/CSP antigen[b]	67	~10	yes	ND
full RV VP8* antigen[c]	231	~20	yes	ND
murine RV VP8* antigen[d]	159	~5	yes	yes
HEV protruding domain antigen[e]	187	~10	yes	ND

*a*HA1 antigen containing the receptor binding site is the head portion of the hemagglutinin (HA) of H7N9 influenza A virus. *b*TSR/CSP antigen is the C-terminal portion of the major surface protein of acircumsporozoite (CSP) that plays a key role in host cell invasion of the malaria parasite Plasmodium falciparum. *c*Full RV VP8*antigen is the full-length VP8*domain of the spike protein of a human P[8] rotavirus. *d*Murine RV VP8*antigen is the core portion of the VP8*protein constituting the head of the spike protein of a murine rotavirus EDIM strain. *e*HEV protruding domain antigen is part of the protruding domain of a hepatitis E virus capsid. *f*Immune enhancements of the S_{60} nanoparticle-displayed antigens were measured in mice using free monomeric antigens as control for comparisons. “ND” = not determined.

S_{60} nanoparticles may serve as a polyvalent vaccine platform (Xia et al. ACS Nano 2018, 12, 10665−10682)

- We believe the self-assembled, polyvalent S_{60} nanoparticle with 60 flexibly exposed S domain C-termini is an ideal vaccine platform for antigen presentation and immunogenicity enhancement.
- This has been supported by studies showing that when Hisx6 tag was fused to the hinge of the S domain via a linker, fusion proteins self-formed into the S_{60} nanoparticles.
- This has also been demonstrated by constructing a chimeric, and reconfirmed by cyroEM density map, S_{60} nanoparticle displaying 60 RV (rotavirus) VP8* proteins, the major rotavirus neutralizing antigen. The S_{60}–VP8*particles can be easily produced with high stability. The chimeric nanoparticle induced higher immunoglobulin, or IgG, response in mice (n=6) toward the displayed VP8*antigen than soluble VP8* antigen. Mouse sera experiments were completed analyzing vaccinated versus the control group to show neutralizing activity against RV infection. The statistical differences between the groups are (*P < 0.05, **P < 0.01, ***P < 0.001) as shown below (Figure 2) (Xia et al. ACS Nano 2018, 12, 10665−10682).
- The RV surface spike protein, VP8* was tested for feasibility of the S_{60} nanoparticle by the analysis using EM micrograph examination and ESI-MS analysis. S_{60}-VP8*particles exhibited stronger blockade in mice (n=6) sera after vaccination (P=0.0003) (Xia et al. ACS Nano 2018, 12, 10665−10682).
- The polyvalent B- and T-cell epitopes of the antigens on the polyvalent VLP platform led to induction of stronger humoral and cellular immune responses, respectively, in animals and humans compared with those elicited by the monovalent epitopes of the free antigen. Thus, the polyvalent VLP platform is likely to increase the immunogenicity of the displayed antigens. Mouse sera experiments were completed analyzing vaccinated versus the control group to show neutralizing activity against RV infection. The statistical differences between the groups are (*P < 0.05, **P < 0.01, ***P < 0.001) as shown below. (Xia et al. ACS Nano 2018, 12, 10665−10682).

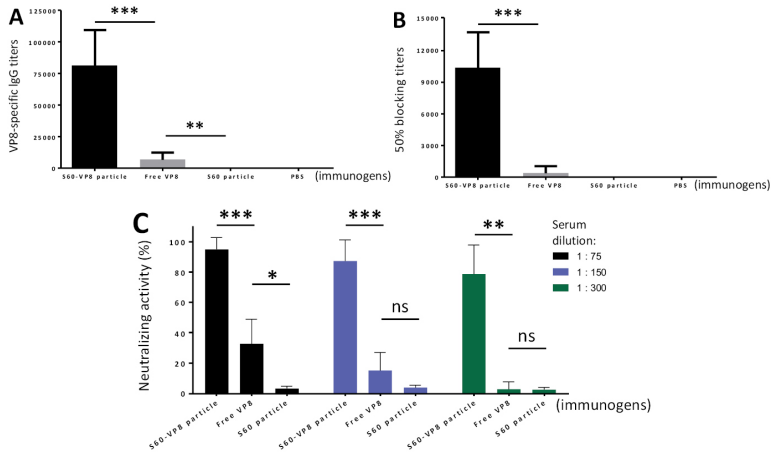


Figure 2. S_{60}-VP8*particles enhanced immunogenicity toward the displayed RV VP8*antigens. The same dose/dosage of the S_{60}-VP8*particles, free VP8*antigens, and S_{60} nanoparticles without VP8*was given to mice (N=6), respectively, followed by measurements of theVP8*-specific IgG responses (A), 50% blocking titers (BT50)

against RV VP8*-glycan ligand interaction (B), and neutralization activity against RV infection/replication in culture cells (C) of the resulting mouse antisera. (A) VP8*-specific IgG responses/titers elicited by theS60-VP8*particles, free VP8*antigens, and the S60nanoparticles, respectively. (B) BT50against RV VP8*−ligand interactions by the mouse sera after vaccination with the same three immunogens, respectively. (C) Neutralizing activity against RV infection/replication in culture cells by mouse sera after immunization with the same three immunogens, respectively. In all these experiments mouse sera after immunization with diluent (PBS) are used as negative controls.

The P_{24} Nanoparticle as a versatile platform (Tan et al. Nanomedicine ,2012. 7.6,1-9)

The crystal structure of norovirus VLPs indicates that P domain is involved in strong dimeric interactions forming dimeric protrusions on the viral surface. The oligomeric interactions of the P domains are also observed at the five-fold axes to further stabilize the capsid structure. When the P domain protein was expressed using the *E. coli* system, it self-assembled into P dimers, as well as 24 valent P nanoparticles, P_{24}. P dimers and P_{24} nanoparticles can exchange dynamically, depending on concentration of the P domain protein, indication that the assembled P_{24} particles at this stage were unstable and easy to disassemble back into P dimers. To facilitate P_{24} nanoparticle formation, inter-P domain disulfide bonds were introduced through fusion of a cysteine-containing peptide to the end of the P domain. During the P_{24} nanoparticle assembly, the cysteine patches were brought to the center of the P_{24} nanoparticles, resulting in sterically close contact and thus forming inter-P domain disulfide bonds that significantly stabilized the P_{24} nanoparticles, which could no longer disassemble back into the P dimers.

- P_{24} nanoparticles can be produced using an *E. coli* expression system faster and a lower cost than VLPs.
- Both VLP and P_{24} nanoparticles without adjuvant produce innate, humoral, and cellular immunity.
- The platform can be used to display foreign antigens, epitopes and viral pathogens and non-infectious disease.
- Studies have demonstrated immune response against flu, rotavirus, and norovirus using bi- or trivalent vaccine candidates developed using this approach, noting the potential for the development of a universal flu vaccine. Pre-clinical studies in influenza and rotavirus are provided below supporting our vaccine candidate programs. See — *Our Infectious Disease Vaccine Candidates*.

Our Infectious Disease Vaccine Candidates

Infectious diseases are one of the leading causes of death worldwide. Infectious disease is caused by microorganisms or pathogens, including viruses, bacteria, fungi, and parasites that infect an individual and cause disease. Diseases often cause high fever, inflammation, or other symptoms. While some diseases can be treated with drugs or therapeutics, some infectious agents evolve to become resistant to commonly used drugs, such as antibiotics, and can become difficult to control. Infectious diseases can be passed from person to person or transmitted by insects or other animals. In many cases, vaccines are used to elicit a protective immune response in the absence of an infection to render an individual immune to a particular infectious disease.

BWV-101: UNIVERSAL INFLUENZA & BWV-102 H1 INFLUENZA

The company's lead 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).

Influenza

Influenza is a viral infection of the respiratory system, causing an infected person to suffer from certain symptoms, including fever, muscle aches, runny nose, cough, congestion, headaches, and fatigue. The four types of influenza viruses include type A, B, C, and D. The type A and B influenza viruses are referred to as human influenza viruses that are primarily responsible for seasonal flu epidemics each year. Type A flu viruses are further divided into two subtypes, named based on differences in two viral surface proteins called hemagglutinin (H) and neuraminidase (N). Influenza types C and D present a lower priority for vaccination, as Type C viruses cause a mild respiratory illness in humans and has not been associated with human epidemics, and Type D viruses primarily affect cattle and are not known to cause illness in humans (*https://www.cdc.gov/flu/about/viruses/types.htm*).

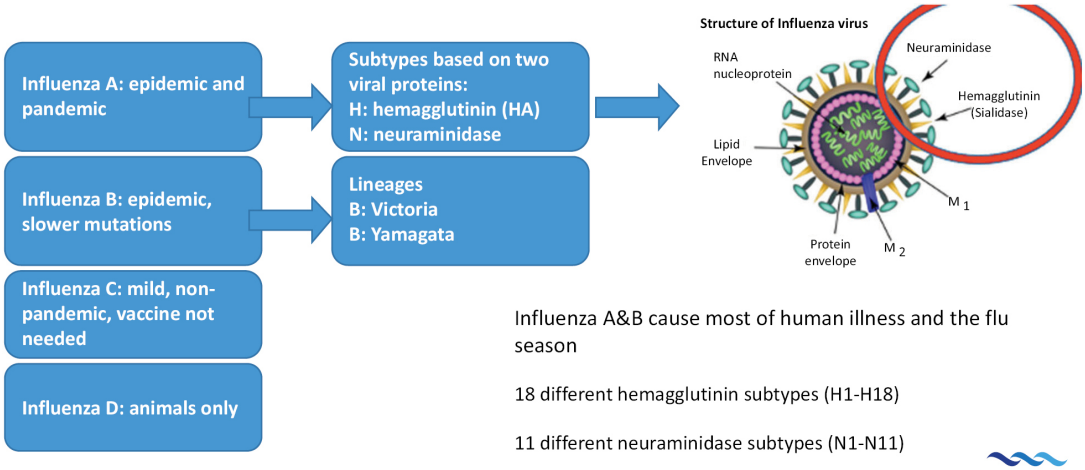


Figure 3. This graphic shows influenza virus types including the two types of influenza viruses (A,B) that cause most human illness and that are responsible for the flu season each year. Influenza A viruses are further classified into subtypes, while influenza B viruses are further classified into two lineages: B/Yamagata and B/Victoria.

There is a major unmet need for the development of a novel universal flu vaccine as a prophylactic therapy. Influenza is a major respiratory pathogen. The WHO estimates there are an estimated 1 billion cases of influenza infection with 3-5 million severe cases and 290,000-650,000 related respiratory human deaths worldwide every year. The estimate does not take into account deaths from other diseases such as cardiovascular disease, which can be influenza related. The next influenza pandemic is believed by many experts to be a potentially devastating global health threat. Influenza mortality rates are highest for the very young and elderly.

The global influenza vaccine market was valued at $3.96 billion in 2018, and is projected to reach $6.20 billion by 2026, representing a CAGR of 5.9% from 2019 to 2026. Currently, the standard of care and most effective protection against flu is through annual vaccination. The WHO estimates that worldwide, approximately $4 billion is spent on influenza vaccines annually. However, the flu also a major cause of work absenteeism, leading to an estimated annual productivity loss in the U.S. of $87 billion. Flu vaccination consists of a yearly injection of attenuated or inactivated (dead) influenza viruses to induce humoral immunity in the form of the antibodies against the current circulating or anticipated seasonal influenza strains. The induction of antibody-producing B-cells through vaccination allows the immune system to defend the body against the influenza virus circulating during the winter months.

An annual seasonal flu vaccine is the best way to help protect against flu. Vaccination has been shown to have many benefits including reducing the risk of flu illnesses, hospitalizations and even the risk of flu-related death in children. The CDC recommends use of any licensed, age-appropriate influenza vaccine during the 2020-2021 influenza season, including inactivated influenza vaccine (IIV), recombinant influenza vaccine (RIV), or live attenuated influenza vaccine (LAIV). No preference is expressed for any influenza vaccine over another. Both trivalent and quadrivalent influenza vaccines will be available. The trivalent vaccines formulation will include A(H1N1) pdm09, A(H3N2) and B/Victoria. The quadrivalent vaccine formulations will include A(H1N1) pdm09, A(H3N2) and B/Victoria, plus B/Yamagata (*https://www.cdc.gov/flu/about/viruses/types.htm*).

The current influenza vaccines induce antibodies that target regions of the virus that are highly variable and have serious shortcomings, as they:

(i) must be administered annually,

(ii) typically provide protection to only 50% of the individuals who receive it; and

(iii) need to be updated annually and reformulated 6 months prior to influenza season, such that strains that are subsequently prevalent during the applicable "flu season" are not protected against by the vaccine.

Our Proprietary Epitope Discovery

Using the technology that we have exclusively licensed from the University of Oxford, we are developing a universal influenza vaccine. Our exclusive license agreements include patented influenza epitopes of limited variability, or ELV, identified through a proprietary computational research and discovery process, discovered by Dr. Sunetra Gupta and her team at the University of Oxford. We have acquired intellectual property for cross-protective epitopes to be used for our vaccine candidates that were developed and identified through a unique computational discovery process at Oxford University. The data produced through computational analysis at Oxford has shown that antigen evolution in influenza is limited to certain regions of the virus that facilitate binding and entry to host cells and these regions of limited antigenic variability are naturally immunogenic and therefore may be used to develop universal immunity to influenza viruses. We have identified epitopes of limited variability in H1 influenza that have circulated throughout history (since 1918) and make ideal vaccine targets and have completed similar analysis of H3 and Flu B strains for similar epitopes which will be used to produce our lead vaccine candidate BWV-101 as a universal vaccine for influenza infection. Due to the cross-reactive nature of the H1 epitopes in pre-pandemic H1 influenza A, we are also pursuing the development of a stand-alone H1 vaccine (BWV-102). These epitopes are able to be formulated into a vaccine candidate using our VLP platform technologies and may be evaluated using other vaccine technologies through partnerships in order to accelerate development of potential vaccines or to explore adjunct therapies (Thompson et al. Nature Communications. 2018. 9:385).

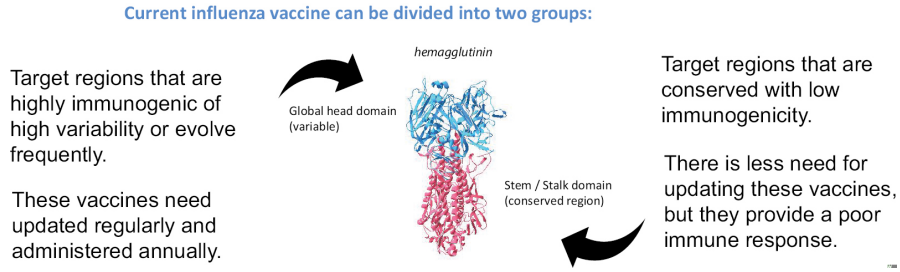


Figure 4. Current influenza vaccine targets.

Antigenic Drift (Thompson et al. Nature Communications. 2018. 9:385)

A single conformational epitope is typically 8 to 15 amino acids in length and in an extreme circumstance (where every change creates an escape mutant), a single epitope could theoretically vary from 208 to 2015 different ways. Therefore, a highly variable virus like influenza should be able to mutate in countless ways during each subsequent season. This would inevitability lead to an explosion of genetic diversity and numerous circulating strains.

However, it seems that there is a constraint limiting how influenza evolves, leading to a single or limited number of strains dominating each season. In 2007, Sunetra Gupta led a group of researchers at the University of Oxford who published a proprietary mathematical model proposing that the single strain dominance, typically seen worldwide annually, could be explained by hypothesizing that epitopes of 'limited variability' exist (Antigenic Drift Hypothesis). The model hypothesizes that while there is a significant amount of mutation of influenza strains, this

variability occurs in a specific portion of the virus, while certain epitopes are required to remain relatively constant and are more limited in their variability in order for the virus to infect individuals, thus clarifying how influenza is not as variable as commonly thought.

Antigenic Drift Hypothesis Illustration

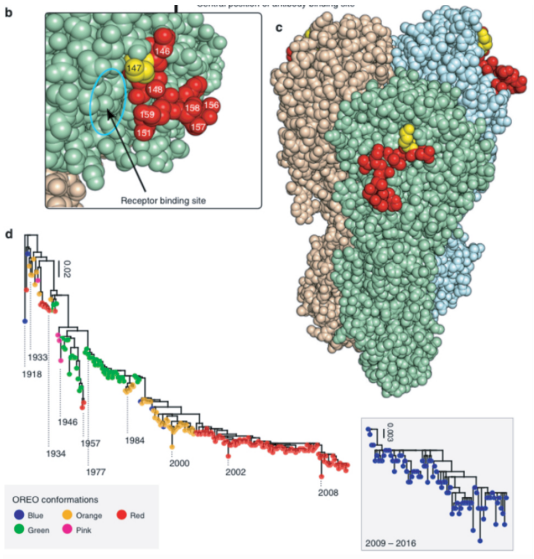


Figure 5. Identification of a site of limited variability in the head domain of the H1 HA..[b,c]Location of ABS of lowest variability containing position 147 with position 147 shown in yellow and the rest of the site colored in red. [d]Phylogenetic trees of pre-pandemic and post-pandemic highlighted rectangle H1N1with tips colored according to the conformation of the epitope of limited variability (hereafter called OREO). Please note the re-introduction of H1N1influenza in 1977 involved a strain which previously circulated in 1949/50.

The Antigenic Drift Hypothesis suggests the existence of epitopes of limited variability mediate a population's immunity to influenza strains. As a particular influenza strain circulates in the population, immunity to a specific pattern of epitopes is induced. This leads the virus to change its antigenic configuration and cycle through its limited repertoire of antigenic conformations. However, population immunity also changes due to birth and death within the population (i.e. individuals in the population who had experienced and developed immunity to certain conformations die). This allows prior epitope conformations to reappear. The loss of herd immunity to these epitope of limited variability causes the emergence of epidemics (*Thompson et al. Nature Communications. 2018. 9:385*).

Oxford scientists have identified the naturally antigenic regions that drive immunity to influenza by evaluating serum from these from various age groups of humans using assays and ELISAs reveal periodic cross-reactivity to ELV. Pseudotype microneutralisation data reveals a cyclical pattern of epitope recognition. The studies of children's sera were used to detect antibodies and demonstrated that young children ages 6 to 12 had immunity to historical influenza strains that circulated many years prior to when they were born and they could never have possibly been exposed to, one of which that last circulated in 1934. Mutagenesis of the identified regions of limited variability in various historical viruses removed the protective immunity. Furthermore, vaccination of mice, as shown below, with these regions of the influenza virus produced an identical immune response that was observed in the children. For example, the mice vaccinated with either the region from the influenza virus circulating in 2006 or 1977 were protected against infection with an influenza with a virus that last circulated in 1934, replicating the immunity seen in children ages 6 to 12. (Thompson et al. Nature Communications. 2018. 9:385)

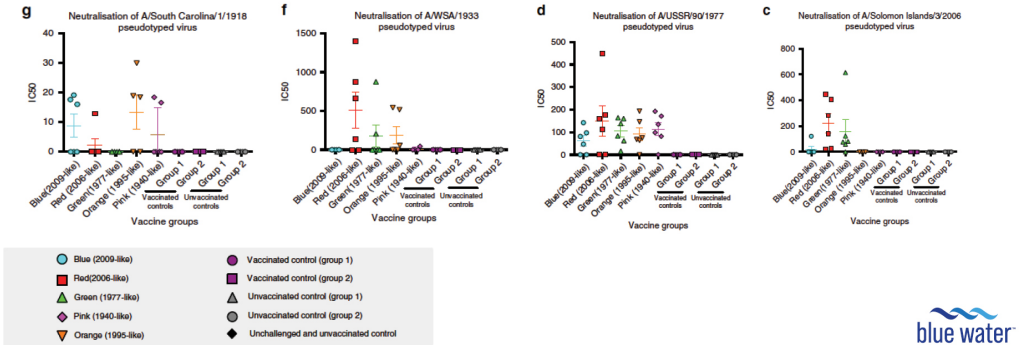


Figure 6. Sequential vaccination using chimeric HA constructs. Five groups of mice were sequentially vaccinated with 2009-like (blue), 2006-like (red),1995-like (orange), 1977-like (green) and 1940-like (pink) epitope sequences substituted into H6, H5 and H11 Has. Two further control groups were sequentially vaccinated with H6, H5 and H11 constructs without any sequence substituted into the Has (vaccinated controls). Further two groups were mock vaccinated (unvaccinated controls). [c,d,f,g]Pseudotype microneutralisation assays using 0.5µl of sera from the bleed at 21 weeks. Error bars are mean ± s.e.m.n=6 for experimental groups and control groups. The values provided are an average of two replicates

This work demonstrated that vaccination with just four variants of one region of limited variability in H1 influenza was able to elicit immunity to all historical H1 influenza strains. As these regions periodically reappear and disappear over time, vaccination with all of the possible variants would be expected to provide protection against future influenza strains as well. The identified epitopes are restricted in their variability due to presence of a receptor-binding site and small alpha helix structure between disulphide bonds.

The following research findings form the basis for our influenza vaccine candidates:

1. Epitopes of limited variability which are under strong immune selection exist within influenza.
2. These epitopes drive the antigenic evolution of influenza.
3. These epitopes cycle between a limited number of different conformations.
4. Epitopes of limited variability would make ideal vaccine targets.

BWV-101: Universal Influenza Vaccine

Our approach to developing a novel, universal flu vaccine for the prevention and protection against human influenza strains and potential pandemic strains by targeting specific limited variability epitopes includes the following steps and processes.

We are exploring development of an influenza vaccine utilizing both the S & P nanoparticles to determine the most effective and efficient presentation of our ELVs and the versatile S&P nanoparticle vaccine platform from CHMC with the H1 influenza antigens. Data in preclinical mice (Rotavirus-specific-antibody-free BALB/c mice, n=5-7) challenge studies inserted M2e, a spike protein of influenza, into a P-particle loop; showed mice that were vaccinated had 100% protection when injected with lethal doses of influenza (Tan et al. JOURNAL OF VIROLOGY, Jan. 2011, p. 753–764). This dual approach will allow us to gain valuable information as we further the development and manufacturing of the BWV-102 program and utilize it for the development of BWV-101. We are currently assessing the ELVs to determine the most effective and efficient route of antigen presentation. Additionally, we are currently optimizing antigens for H3 and Flu B to be included with the identified H1 antigens to finalize our universal influenza vaccine formulation.

We are using established manufacturing methods, including *E.coli* fermentation to produce our chimeric proteins, to reduce the cost and increase the efficiency and scalability of our manufacturing process for the vaccine. The antigens will be displayed by a proprietary virus-like particle (VLP) that can be produced in *E. coli* (Pharmaceutics 2019, 11, 472; doi:10.3390/pharmaceutics11090472). Our research and discovery model uses bioinformatics and phylogenetic analysis to identify possible sites of epitopes of limited variability before confirming their existence experimentally.

To date, we have identified naturally immunogenic epitopes for H1, H3 and influenza B. Bioinformatics studies and wet lab studies suggest that these epitopes, especially H1N1, and the chimeric scaffold configuration of our vaccine induce immunity due to induction of broad cross-reactive antibodies in other strains such as H10N3 (bird flu), and pandemic strains including H5NX, H7NX, and H9NX. H9NX (Thompson et al. Nature Communications. 2018. 9:385). Therefore, we foresee the development of H1N1 vaccine as a priority due to its high cross-reactive priorities.

BWV-102 Stand-Alone H1 Vaccine

We are developing our H1 stand-alone influenza prophylactic product, BWV-102, to address potential pandemic zoonotic H1 strains, specifically the G4 EA H1N1 identified by scientists and reported in June 2020, as a potential next pandemic strain. BWV-102 is being developed using the H1 ELVs identified by the team at the University of Oxford. While the product is designed to protect against infection from any H1 strain, there is potential for cross protection from H5 and H10 strain infections as well. Preclinical studies were conducted in Balb C mice (n=6) using a prime-boost-boost protocol (Thompson et al. Nature Communications. 2018. 9:385). The proposed Phase I clinical study will employ this prime – boost protocol; however, it is possible that a single dose of the vaccine candidate will confer protection against current and historical H1 strains with a prime-boost dose or a single dose.

As reported in 2020, the G4 EA H1N1 strain is the most prevalent influenza strain circulating among swine populations in China. The strain was first identified in 2016 and has been monitored by scientists in China through their swine surveillance program. The strain has genes from a mix of pig, avian and human viruses, including genes from the 2009 H1N1 flu pandemic virus. Currently, the G4 EA H1N1 strain is not transmissible human to human, however, scientists hypothesize that there is a high likelihood of strain reassortment occurring that could make human to human transmissibility possible. The current H1N1 influenza strain circulating may provide some protection against disease induced by G4 EA H1N1 infection.

The ability of the BWV-102 ELVs to induce an immune response and protection against heterologous challenge with historical strains was assessed in Balb-C mice (n=6) (*Thompson et al. Nature Communications. 2018. 9:385*). We are currently assessing the ELVs in combination with the S_{60} particle, P_{24} particle and a proprietary VLP, currently in development, to determine the most effective and efficient route of antigen presentation. Manufacturing of the product is expected to occur in *E. coli (Pharmaceutics 2019, 11, 472; doi:10.3390/pharmaceutics11090472)*. We anticipate results of the VLP presentation assessments in the first half of 2022.

BWV-201 Streptococcus pneumoniae (S. pneumoniae) Vaccine

Our BWV-201 vaccine candidate is a live attenuated serotype-independent vaccine, for which early data supports further investigation to pursue a long-term preventive intranasal vaccine for *S. pneumoniae* induced acute otitis media, or AOM. We in-licensed the novel live attenuated *S. pneumoniae* strain from St. Jude Children's Research Hospital, or St. Jude, as a potential serotype independent vaccine.

The potential of this vaccine to provide a long-term, leading alternative treatment for AOM and subsequent introduction of a novel preventative standard of care. The development of a novel vaccine could eradicate potential short-term pain and/or long-term harmful side effects from contracting the virus. Complications from AOM include sensorineural hearing loss, or SNHL, in adults but are more relevant for the endangerment of children.

Researchers from St. Jude developed a strain of *S. pneumoniae* that contains greatly reduced virulence yet can transiently colonize the nasopharyngeal cavity, inducing immune responses to significantly decrease the incidence of AOM and sinusitis as demonstrated in animal models. Our vaccine production is a straightforward process, utilizing the entire novel attenuated bacterium with purification and concentration steps only in the downstream process, thereby reducing the time and cost of production significantly compared to commonly used polysaccharide or conjugate vaccines.

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. AOM is the most common condition treated with antibiotics in the United States and increasing antibiotic resistance among the organisms responsible for AOM is of concern to researchers.

Additional statistics supporting the need for a novel preventive vaccine:

- The global AOM rate is 10.85%, or 709 million cases per year, with 51% occurring in children under 5 years old (Tong et al. BMC Health Serv Res. 2018; 18: 318).
- By 3 years of age, 80% of children globally are expected to have at least one episode of AOM. (Vergison A, Lancet Infect Dis. 2010 Mar;10(3):195-203. doi: 10.1016/S1473-3099(10)70012-8. PMID: 20185098.).
- Current treatment for AOM is by antibiotic prescription, with more than 80% of all consultations resulting in a prescription. (Haggard, M. Eur J Pediatr 170, 323 – 332 (2011). *https://doi.org/10.1007/s00431-010-1286-4*).
- Even with the introduction of the pneumococcal conjugate vaccine (PCV13) in 2010, 26-36% of cases of AOM in U.S. were caused by *S. pneumoniae.* (Casey JR, Kaur R, Friedel VC, Pichichero ME. Acute otitis media otopathogens during 2008 to 2010 in Rochester, New York. *Pediatr Infect Dis J*. 2013;32(8):805-809. doi:10.1097/INF.0b013e31828d9acc).
- Worldwide cases of AOM due to *S. pneumoniae* is estimated to be 30-50%. (Bergenfelz C, Hakansson AP. Curr Otorhinolaryngol Rep. 2017;5(2):115-124. doi: 10.1007/s40136-017-0152-6. Epub 2017 May 20. PMID: 28616365; PMCID: PMC5446555.).
- An estimated $4.3 billion USD is spent on AOM treatment each year in the U.S. alone. (Tong S, BMC Health Serv Res. 2018 May 2;18(1):318. doi: 10.1186/s12913-018-3139-1. PMID: 29720156; PMCID: PMC5932897.).

The current standard of care treatment for AOM in children is reliant on antibiotics. The resolution rate of AOM in children is 81% without antibiotic treatment vs. 93% with antibiotic treatment. Antibiotic treatment of AOM in children has limitations, including recurrence within 30 days.

The CDC recommends broad pneumococcal vaccines for children younger than 2 and for adults over 65 years of age (CDC). The CDC also recommends vaccinations for children and adults age 2 through 64 either previously unvaccinated or partially vaccinated. Two vaccines are currently approved in the U.S. and other countries: Prevnar13 or PCV13 (Pfizer) (ii) Pneumovax or PPSV23 (Merck). An additional vaccine, Synflorix, is for approved use outside of the U.S. for the prevention of pneumococcal disease and *S. pneumoniae* induced AOM for the 10 serotypes included in the vaccine.

Therefore, an effective serotype independent *S. pneumoniae* AOM vaccine could significantly impact pediatric healthcare demand. As a preventative treatment, the vaccine’s advantages include: reduction of near-term pain; reduction of recurrent AOM that may result in the need for tympanostomy tube placement; lessening of antibiotic usage, which would decrease the number of antibiotic resistant organisms in the environment; and avoiding potential long-term hearing loss.

Previous live, attenuated strains of S. pneumoniae were generated by deleting several highly immunogenic virulent genes and therefore may not be optimal vaccine candidates. Some of these deletions include antigens that induce antibody responses following pneumococcal carriage and otitis media in young children and therefore may not be optimal vaccine candidates.

Our technology in-licensed from St. Jude focuses on candidate genes essential for microbial adaptation to the host environment while maintaining virulence determinants. The St. Jude researchers developed a *S. pneumoniae strain* with a deletion in *ftsY*, a central component of the signal recognition pathway (SRP). SRP mutants have greatly reduced virulence, although virulence factors are still produced. The *S. pneumoniae ftsY* deletion strain may potentially make an ideal live attenuated vaccine, as it can transiently colonize the nasopharyngeal cavity without inducing immune responses to virulence protein antigens but does not cause invasive disease.

Our candidate vaccine is a live attenuated serotype-independent vaccine, that early data supports further development to pursue a potential long-term preventive intranasal treatment. BWV-201 will likely require two doses to provide life-long protection. BWV-201's has the ability to transiently colonize the nasopharyngeal cavity and significantly decrease the incidence of AOM and sinusitis in animal models. The vaccine candidate is derived from the noninvasive serotype 19F strain BHN97, which normally causes sinusitis/purulent rhinitis and AOM. As previously noted, the *ftsY* gene was deleted by St. Jude researchers, and is designated BHN97DftsY (Rosch, Jason W et al. EMBO molecular medicine vol. 6,1 (2014): 141-54. doi:10.1002/emmm.201202150).

Our vaccine production is a straightforward approach, utilizing the entire bacterium with purification and concentration steps only in the downstream process thereby significantly reducing the time and cost of production compared to polysaccharide or conjugate vaccines.

Preclinical data colonization and invasiveness and Otitis Media/Sinusitis Efficacy

Our pre-clinical data has shown encouraging results from the research and development of BWV-201 as a potential intranasal delivered vaccine candidate. Multiple animal models have demonstrated protection from AOM.

To demonstrate vaccine efficacy against AOM and sinusitis, mice were immunized (prime and two boosts) with Prevnar 7, Prevnar 13, Pneumovax, D39x and BHN197 caxP and ftsY deletion mutants. Deletion of ftsY, a central component of the signal recognition particle (SRP) pathway show heightened sensitivity to environmental stress and have greatly diminished virulence. Deletion of caxP, a calcium/magnesium transporter, renders host physiological conditions in blood and mucosa toxic to the bacterium. BHN97ftsY serotype 19F is also characterized in PCV7, PCV13, and PCV23 (Rosch, Jason W et al. EMBO molecular medicine vol. 6,1 (2014): 141-54. doi:10.1002/emmm.201202150).

This head-to-head preclinical study mice (n=25-31) that were either vaccinated by mock or live attenuated with deletions of either type 2 or 19F backgrounds. This was challenged by bioluminescent BMH97X twice daily for AOM and sinusitis. Histopathology was also used to analyze the ears of mice. Xenogen imaging PPV23 was used as a negative control.

Two weeks following the second boost, the bioluminescent strain BNH97x (type 19F), a serotype included in Prevnar 7, Pneumovax and BHN97ftsY (referred to as homologous challenge) were introduced to the mice. Only BHN97ΔftsY, and to a lesser extent Prevnar 7, showed significant reduction in AOM and only BHN97ΔftsY demonstrated significantly reduced sinusitis compared to mock infected animals. The incidence of AOM was significantly ($p < 0.05$ compared to mock) lower in BHN97ΔftsY – vaccinated mice (Figure A-below). Only BHN97ΔftsY vaccine significantly decreased the incidence of sinusitis ($p < 0.05$). Measurement of luminescence at 24 and 72 h confirmed protection engendered by BHN97ΔftsY.

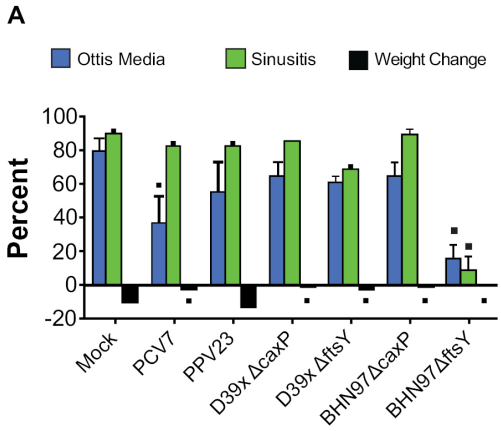


Figure 7. Vaccine protection against otitis media and sinusitis. Mice (n=25–31 per group, performed at least twice for each group) were mock-vaccinated with PBS (Mock) or vaccinated with live attenuated vaccines deleted for caxP or ftsY on either a type2 (D39DcaxP, D39DftsY) or type19F (BNH97DcaxP, BNH97DftsY) background. Mice were challenged with a bioluminescent *S. pneumoniae* strain BNH97X (type19F) and imaged twice daily for development of AOM or sinusitis. A. The proportion of mice developing an infection of the ear or sinus by Xenogen imaging. * =p<0.05 by Chi-squared test compared to the mock vaccinated group. PPV23 was used as a negative control (60% otitis and 80% sinusitis). Errors bars represent standard error of the mean.

To determine if BHN97DftsY (serotype 19F) can induce heterotypic AOM protection (AOM caused by a *S. pneumoniae* serotype not contained in the vaccine), mice (n=20) were immunized as detailed above and challenged with BHN54 (serotype 7), which causes otitis media in about 50% of challenged animals. The control vaccine Prevnar 13 contains serotype 7; therefore, this study compares heterotypic (BHN97DftsY) versus homotypic (Prevnar 13) vaccine protection. BHN97DftsY had a 10-fold lower incidence of AOM, (*p < 0.05) when compared to mock immunized animals, demonstrating that the attenuated vaccine does induce heterotypic protection. Bioluminescent signaling as well as, reduction in weight loss also demonstrated secondary analysis supporting vaccine protection.

BHN97DftsY induced protection from AOM was additionally confirmed in a chinchilla (n=20) animal model. The animals were immunized (prime and two boosts) and then challenged with BHN97 two weeks after the final boost. Vaccinated animals had a decreased incidence of culture-positive ears and had a significantly decreased number of recoverable bacteria from the middle ear (A). Following vaccination, a reduction in the number of culture positive ears in vaccinated group compared to the mock animals was observed (B) as well as significant reduction in recoverable CFUs from middle ear 7 days post challenge (C) * = p < 0.05 by Mann–Whitney.

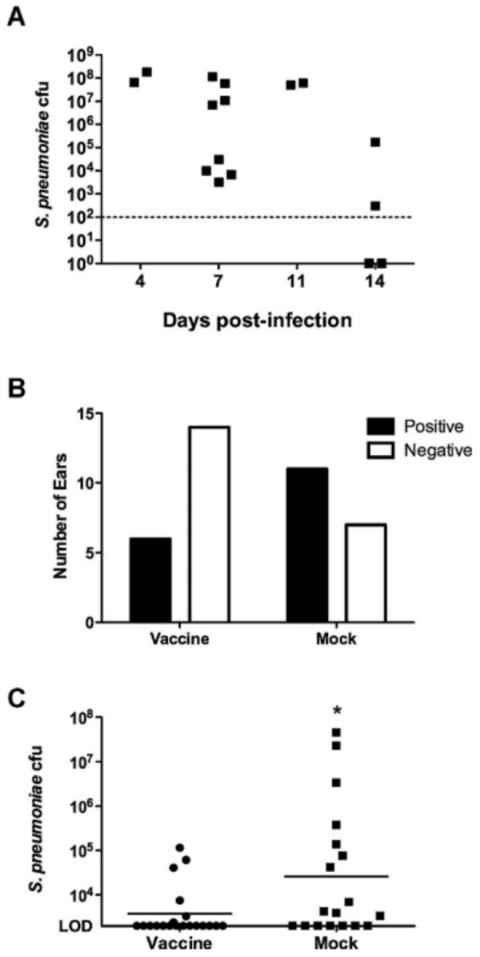


Figure 8. Vaccine protection in a chinchilla model of otitis media. The BHN97strain is capable of causing otitis media in chinchillas via intranasal administration as observed by recoverable bacterial colony forming units (CFUs) from the middle ear (A) following challenge. B, C Following vaccination, a reduction in the number of culture positive ears in the vaccinated group compared to the mock animals was observed (B) as well as a significant reduction in recoverable CFUs from the middle ear at 7days post challenge (C). * =p<0.05by Mann–Whitney.

A potential advantage of an attenuated *S. pneumoniae* vaccine such as BHN97DftsY is that immune responses are directed to bacterial proteins rather than just polysaccharides and should not be limited to serotype specific protection. Purified polysaccharide (PPV) vaccines such as Pneumovax (produced by Merck &Co.) and pneumococcal conjugate vaccines such as Prevnar 7/13/20 (produced by Wyeth/Pfizer) or Synflorix (produced by GlaxoSmithKline plc) are generally considered serotype specific, inducing protection to disease caused only by pneumococcal strains contained in the vaccines.

BWV-301 Norovirus-Rotavirus Vaccine Program

We are developing BWV-201 to prevent acute gastroenteritis, or AGE, caused by norovirus and rotavirus, utilizing the P_{24} nanoparticle of our vaccine platform. The vaccine is based on one or two doses of the norovirus P_{24} nanoparticle presenting 24 rotavirus VP8* antigens. Most cases of gastroenteritis are caused by viruses. The CDC reports that viral gastroenteritis infections cause 200,000 deaths in children worldwide each year. Common symptoms of viral gastroenteritis causes nausea, vomiting, diarrhea, anorexia, weight loss, and dehydration.

Gastroenteritis

Gastroenteritis, often called stomach flu, is inflammation of the gastrointestinal tract — the stomach and intestine. Symptoms may include diarrhea, vomiting and abdominal pain. Fever, lack of energy and dehydration may also occur. While gastroenteritis is usually caused by viruses, bacteria, parasites, and fungus can also cause gastroenteritis. Eating improperly prepared food, drinking contaminated water or close contact with a person who is infected can spread the disease. Norovirus and rotavirus are two viruses that cause gastroenteritis in adults and children.

In 2015, there were two billion cases of gastroenteritis, resulting in 1.3 million deaths globally. Children and those in the developing world are affected the most. In 2011, there were about 1.7 billion cases, resulting in about 700,000 deaths of children under the age of five. In the developing world, children less than two years of age frequently get six or more infections a year. It is less common in adults, partly due to the development of immunity. In adults, norovirus is the most common cause of severe disease. Rotavirus, however, is the common cause of AGE in children.

Norovirus

Norovirus causes significant debilitating AGE, with a reported 700 million infections and 20% of all diarrheal cases reported annually worldwide, according to the CDC. About 200 million cases are seen among children under 5 years old, leading to an estimated 50,000 child deaths every year. Norovirus is the cause of approximately 20% of all AGE cases worldwide each year. It is estimated that 68.9 cases of norovirus infection occur in every 1000 people. In North America, norovirus induced AGE tends to be seasonal, occurring in cooler, rainy months and particularly impacts groups in close proximity, such as in schools, dormitories, medical facilities, and cruise ships.

Norovirus costs $60.3 billion worldwide each year (CDC). Globally, norovirus resulted in a total of approximately $4.2 billion in direct health system costs and approximately $60.3 billion in societal costs per year. Disease among children younger than 5 years cost society $39.8 billion, compared to $20.4 billion for all other age groups combined. Costs per norovirus illness varied by both region and age and was highest among adults ages 55 years and older. Productivity losses represented 84-99% of total costs varying by region. While low and middle income countries and high income countries had similar disease incidence (10,148 vs. 9,935 illness per 100,000 persons), high income countries generated 62% of global health system costs (Bartsch et al. PLoS One 2016; 11:e0151219).

In North America, the median yearly cost of outbreaks was $7.6 million in direct medical costs, and $165.3 million in productivity losses. An average of approximately 113,000 hospitalizations, 8.2-122.9 million missed school/work days, $0.2-$2.3 billion in direct medical costs, and $1.4-$20.7 billion in productivity losses was due to sporadic illness. The total economic impact of norovirus infection was $10.6 billion based on the current incidence estimate 68.9 cases per 1000 population, or approximately $0.15 million per person infected.

The total economic burden is greatest in young children but the highest cost per illness is among older age groups in some regions. These large costs overwhelmingly are from productivity losses resulting from acute illness. Low, middle, and high income countries all have a considerable economic burden, suggesting that norovirus gastroenteritis is a truly global economic problem.

There is not a norovirus vaccine on the market presently. There are, however, a number of rotavirus vaccines currently marketed around the world. RotaTeq, owned by Merck, a live, oral pentavalent vaccine and Rotarix, owned by GSK, a monovalent, human, live attenuated vaccine are recommended by the World Health Organization (WHO) for global use in children and approved for use in the U.S., Canada and Europe. Other monovalent vaccines are available but only approved for use in one country, either China, Vietnam or India.

Development

P_{24} VLPs produced in *E. coli* and norovirus VP1 VLPs produced in a baculovirus expression system were both demonstrated to elicit innate, humoral and cellular immunity in a mouse model, indicating that both constructs have potential as norovirus virus candidates. In addition, when delivered intranasally both constructs were able to induce partial cross-variant protection against diarrhea in a gnotobiotic pig model. Ramesh et al. *Vaccines* 2019, 7, 777.

Rotavirus

Rotavirus is the most common cause of diarrheal disease among infants and young children, causing an estimated 111 million episodes of diarrhea annually, 2 million hospitalizations and 352,000-592,000 deaths annually, according to the CDC. After the introduction of live attenuated oral vaccines the incidence of rotaviral hospitalizations and deaths have significantly declined. However, there is still a need for efficacious, cost-effective rotavirus vaccines.

The rotavirus vaccine is recommended by the CDC and ACIP as a prevention for children. However, managing the symptoms is the only way to help adults and children infected with either of the viruses. Due to the potential of death, most treatments are focused on dehydration prevention and management. Treatment involves getting enough fluids. For mild or moderate cases, this can typically be achieved by drinking oral rehydration solution (a combination of water, salts and sugar). In those who are breastfed, continued breastfeeding is recommended. For more severe cases, intravenous fluids may be needed and care provided in the hospital. Fluids may also be given by a nasogastric tube. Zinc supplementation is recommended in children. Antibiotics are generally not needed. However, antibiotics are recommended for young children with a fever and bloody diarrhea.

To determine the potential of the P_{24} VLP to serve as a rotavirus vaccine candidate, the 159 amino acid VP8* protein was inserted into a P_{24} domain surface loop. The fusion proteins self-assembled into P_{24} VLPs, and the 24 rotavirus VP8* antigens were demonstrated by cryo-EM to be displayed on the outermost surface of the chimeric P_{24} VLP. Mice (n-5-7) immunized intranasally with the P_{24}-VP8* or intramuscularly with Freund's adjuvant elicited significantly higher rotavirus neutralizing antibodies than the free VP8* immunized under the same conditions (IN or IM). (P >0.05), (Tan et al. J. Virol. 85(2):753-764. 2011.

P_{24}-VP8* VLPs were further characterized as a potential rotavirus vaccine in mouse and gnotobiotic pig challenge studies. A construct consisting of P_{24} and the VP8* antigen from the murine rotavirus EDIM strain was constructed and tested using a murine rotavirus challenge model. Mice (n=5-7) were immunized with P_{24}-mouseVP8*, mouseVP8* alone or P_{24}-human VP8* 3 times intranasally without adjuvant. Rotavirus shedding was significantly lower in animals immunized with P_{24}-mouseVP8* than mock vaccinated or animals that received mouseVP8* only or P_{24}-humanVP8* * (P >0.05) (Tan et al. J. Virol. 85(2):753-764. 2011).

Additionally, an immunogenicity study was conducted in gnotobiotic pigs (n=25). A construct of P_{24} and the VP8* antigen corresponding to human rotavirus Wa strain was tested in a gnotobiotic pig challenge model. Animals were immunized intramuscularly (IM) three times with either P_{24}-WuVP8* with luminium hydroxide adjuvant or luminium hydroxide alone and were challenged with human Wa rotavirus 7 days post dose three. Animals immunized with P_{24}-WuVP8* showed a significant reduction in the mean duration of diarrhea, virus shedding and significantly lower fecal cumulative consistency scores compared to adjuvant only control group (*, p < 0.05; **, p < 0.01). (Ramesh et al. Vaccines 7: 177 2019; doi:10.3390/vaccines7040177).

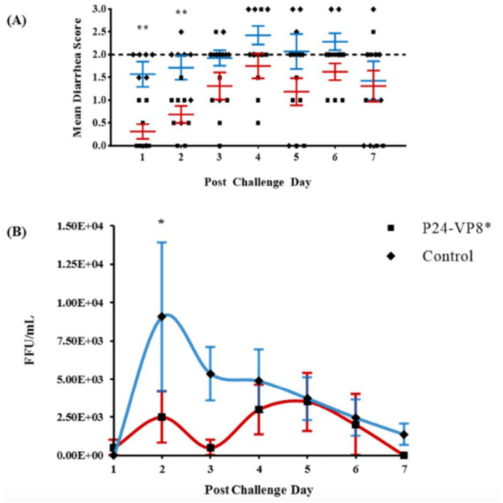


Figure 9. .P24-VP8* vaccine protected against VirHRV diarrhea and reduced overall virus shed among vaccinated pigs. Fecal consistency (A) and virus shedding (B) were monitored daily from post challenge day (PCD) 1 to PCD 7 after the challenge with VirHRV. Fecal consistency scores≥2 were considered to be diarrheic (dashed line indicates the threshold of diarrhea). Statistical significance between vaccinated and control groups, determined by multiple t tests, are indicated by asterisks (*,p<0.05; **,p<0.01).

Additionally, serum samples were collected from the pigs at the times of P_{24}-VP8* vaccine administration (PID 0, PID 10, PID21 and PID 21) and VirHRV challenge (PID 27) and upon euthanasia (PCD 7). The P_{24}-VP8* vaccine was highly immunogenic in Gn pigs. It induced strong VP8*-specific serum IgG and Wa-specific virus-neutralizing antibody responses from post-inoculation day 21 to PCD 7. Comparisons between groups at the same time points were carried out using Student's t-test and significant differences are identified by *** (n = 10 – 15; p < 0.001). Tukey-Kramer HSD was used for the comparison of different time points within the same group, where different capital letters (A, B, C,D) indicate a significant difference, p < 0.01, and shared letters indicate no significant difference. These findings support further investigation of the noro-rotavirus dual nanoparticle vaccine. (Ramesh et al. Vaccines 7: 177 2019; doi:10.3390/vaccines7040177)

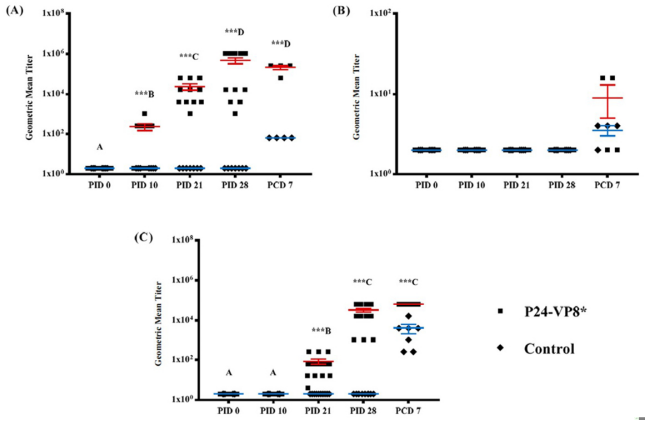


Figure 10. Geometric mean VP8*-specific IgG (A) and IgA (B) andWa-HRV neutralizing (C) antibody titers in serum collected from Gn pigs at PID 0, 10, 21, 28, and PCD 7. Pigs were vaccinated with P24-VP8* vaccine or Al(OH)3 adjuvant only. Each serum specimen was tested at an initial dilution of 1:4. Negative samples were assigned an arbitrary value of 2 for calculation and graphical illustration purposes. Comparisons between groups at the same time points were carried out using Student's t-test and significant differences are identified by *** (n = 10–15; p < 0.001). Tukey-Kramer HSD was used for the comparison of different time points within the same group, where different capital letters (A, B, C, D) indicate a significant difference, p < 0.01, and shared letters indicate no significant difference.

An effective norovirus culture-based neutralization assay is not available, due to the lack of an efficient cell culture system to produce human norovirus. Therefore, a surrogate neutralization assay has been developed in the field, measuring the ability of antisera to block norovirus VLP binding to host receptors. In addition to generating rotavirus neutralizing antibody, Tan et al (J. Virol. 86:753-764. 2011) demonstrated that anti- P_{24}-VP8* mouse sera blocked norovirus VLP binding, indicating that the insertion of the VP8* fragment did not inhibit induction of norovirus VLP binding antibodies and suggesting the P_{24}-VP8 construct could potentially serve as a single vaccine against both rotavirus and norovirus disease (P >0.05).

Our Vaccine

We hold the exclusive global license for the novel norovirus-rotavirus combination vaccine (except in China and Hong Kong) from Cincinnati Children's Hospital Medical Center, or CHMC, CHMC researchers engineered the norovirus major structural protein VP1 such that the N-terminal shell (S) and C-terminal protruding (P) domains of VPI could be expressed as separate S_{60} and P_{24} virus-like particles (VLPs). Unlike norovirus VLPs composed of the intact VP1 protein or the unmodified S_{60} fragment, our S_{60} and P_{24}VLPs can be expressed in *E. coli*. The researchers

demonstrated that S_{60} VLPs could be used to present foreign antigens on the surface of the S_{60} VLP. Further, it has also demonstrated that foreign antigens could also be expressed on the surface of the P_{24} VLP. The proposed norovirus-rotavirus vaccine is based on the P_{24} VLP technology. Our vaccine production is based on an *E.coli* expression platform.

Development

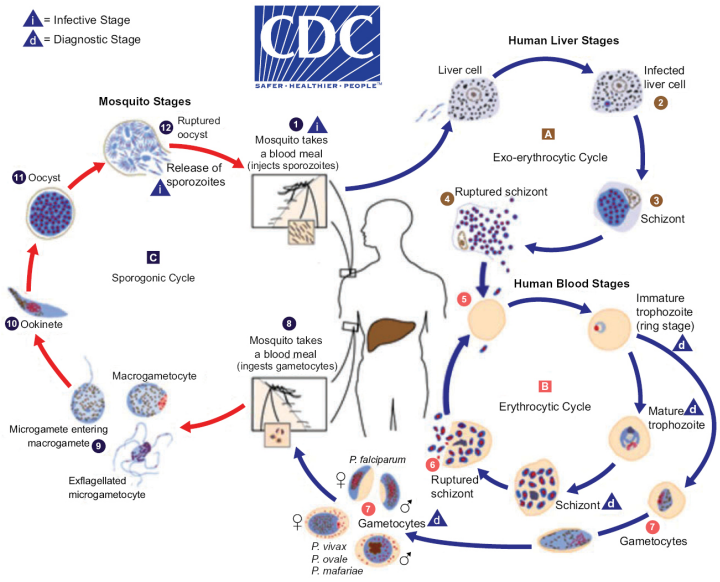
Following IND submission, if accepted, we intend to initiate our Phase I clinical trial in healthy adults ages 18 to 54. If approved, we believe our vaccine is well positioned to receive a recommendation from the CDC, ACIP, and similar international advisory groups for inclusion in vaccine programs.

BWV-302: Norovirus-malaria vaccine program

Additionally, we are currently investigating a malaria vaccine, BWV-302, utilizing our norovirus 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. Preclinical study results testing our vaccine design are expected in 2022.

Malaria

Malaria can be a deadly disease caused by protozoan parasites from the Plasmodium family, primarily spread by mosquitos (CDC, https://wwwnc.cdc.gov/travel/diseases/malaria). Malaria may also, at times, be transmitted through blood transfusion, organ transplantation and from mother to fetus. (CDC, *https://wwwnc.cdc.gov/travel/yellowbook/2020/travel-related-infectious-diseases/malaria*). While transmission through blood transfusion is rare in the U.S., there are no approved blood tests currently available to screen blood donation for malaria. There were approximately 219 million cases of malaria reported in 2019 globally, resulting in approximately 409,000 deaths, of which approximately 67% were children. (WHO, *https://www.who.int/news-room/fact-sheets/detail/malaria*). Symptoms of malaria normally manifest themselves within 7 to 10 days of exposure, and can at times, be mistaken for other illnesses, including influenza. Severe malaria is life-threatening and can cause multi-organ failure in adults and severe anemia, metabolic acidosis and cerebral malaria in children. The World Health Organization estimates that almost half of the global population is at risk of contracting malaria. Infants, children under 5 years of age, pregnant women and immune compromised individuals are highest risk of developing the disease. Additionally, non-immune migrants, mobile populations and travelers are at risk of developing severe disease. Neurological issues in children may continue to persist after cerebral malaria, including ataxia, palsey, speech impairment, deafness and blindness.



More than 100 species of Plasmodium have been identified. Four of the species have been recognized as naturally infecting humans, while one that infects macaques and has been identified as a cause of zoonotic malaria. In rare cases, additional species may infect humans. The primary four parasites that cause human infection are *P. falciparum, P. vivax, P. ovale and* (*https://www.cdc.gov/malaria/about/biology/index.html*). *P. knowlesi* is naturally occurring in macaques in Southeast Asia and has recently been reported as the cause zoonotic malaria, especially in Malaysia. *P. falciparum* is found world-wide, can cause severe malaria and is the predominate human malaria causing species around the world.

There is currently one vaccine for malaria, RTS,S/AS01 (MVI-GSK) targeting the falciparum CS protein, which received a positive opinion from the European Medicines Agency (EMA) for use outside of the European Union in infants 6 weeks of age and older. (*https://www.ema.europa.eu/en/news/first-malaria-vaccine-receives-positive-scientific-opinion-ema*) According to the EMA, the World Health Organization and the relevant regulatory agencies for countries outside of the European Union can authorize its use. The vaccine is currently being administered to infants and children in parts of Africa within high transmission regions The vaccine's efficacy appears to wane after five years (Laurens MB. RTS,S/AS01 vaccine (Mosquirix™): an overview. *Hum Vaccin Immunother.* 2020;16(3):480-489. doi:10.1080/21645515.2019.1669415). The recommended course of action for preventing malaria is prevention of mosquito bites, and for those most vulnerable, a preventative treatment with sulfadoxine-pyrimethamine, especially in high transmission areas (WHO). In certain regions, the WHO has recommended the addition of amodiaquine to children under 5 years of age monthly during the high transmission season, along with sulfadoxine-pyrimethamine. Many regions employ mosquito control measures to reduce mosquito populations, however, 73 countries have reported mosquito resistance to at least 1 of the 4 most commonly used insecticides, while 23 countries have reported mosquito resistance to all of the commonly used insecticides.

Once malaria is diagnosed, the two most common treatments are Chloroquine phosphate and Artemisinin-based combination (ACT) therapies. Chloroquine is the preferred treatment, however, some malaria parasites have become resistant to chloroquine and it may not be an effective treatment. ACT is a combination of two or more drugs that work against the malaria parasite in different ways. This is usually the preferred treatment for chloroquine-resistant malaria. However, as recently reported in Nature Medicine, there is growing concern about Artemisinin – derivative resistant P.falciparum in the Greater Mekong subregion (Cambodia, Thailand, Vietnam, Myanmar and Laos) (*https://www.nature.com/articles/s41591-020-1005-2.pdf*). Previous occurrences of resistant strains also first appeared in the Greater Mekong subregion and then spread to other parts of the world. (*https://www.nature.com/articles/s41591-020-1005-2.pdf*).

Our Vaccine

We hold the exclusive global license for the novel norovirus-malaria combination vaccine from Cincinnati Children's Hospital Medical Center, or CHMC, CHMC researchers engineered the norovirus major structural protein VP1 such that the N-terminal shell (S) and C-terminal protruding (P) domains of VPI could be expressed as separate S_{60} and P_{24} virus-like particles (VLPs). Unlike norovirus VLPs composed of the intact VP1 protein or the unmodified S_{60} fragment, our S_{60} and P_{24}VLPs can be expressed in *E. coli*. The researchers, Xi Jason Jiang, Ph.D., and Ming Tan, Ph.D., demonstrated that S_{60} VLPs could be used to present foreign antigens on the surface of the S_{60} VLP. Further, it has also demonstrated that foreign antigens could also be expressed on the surface of the P_{24} VLP. (see disclosure ***BWV Norovirus (NoV) S&P Nanoparticle Versatile Vaccine Platform*** on pages 82 through 86). The proposed norovirus-malaria vaccine, P-CS□TSR is based on the P_{24} VLP technology. Our vaccine production is based on an *E.coli* expression platform.

The circumsporozoite (CS) protein is the major surface component of *P. falciparum* sporozoites and is essential for host cell invasion. Our vaccine, developed by Jiang and Ming from CHMC, combines a small domain of the CS protein with the norovirus P_{24} particle creating a chimeric nanoparticle capable of eliciting an immune response. A mouse immunization study was conducted using the P_{24} particle presenting the small domain of the CS protein. Mice (n=16) were immunized three times with the chimeric nanoparticle using aluminum hydroxide as an adjuvant, 3D7-His, 3D7-GST and PBS. Sera was collected and evaluated.

High antibody titers, as determined by ELISA, were observed after the second immunization and higher titers were observed after the third immunization. The antibodies were also shown to recognize the plasmodium falciparum 3D7 strain using immunofluorescence assays. These data demonstrate the potential of our vaccine candidate against malaria. We expect to conduct an animal challenge study to further analyze the protective nature of BWV-302 and support an IND application.

Table 3. Mouse malaria antibody titer post-immunization

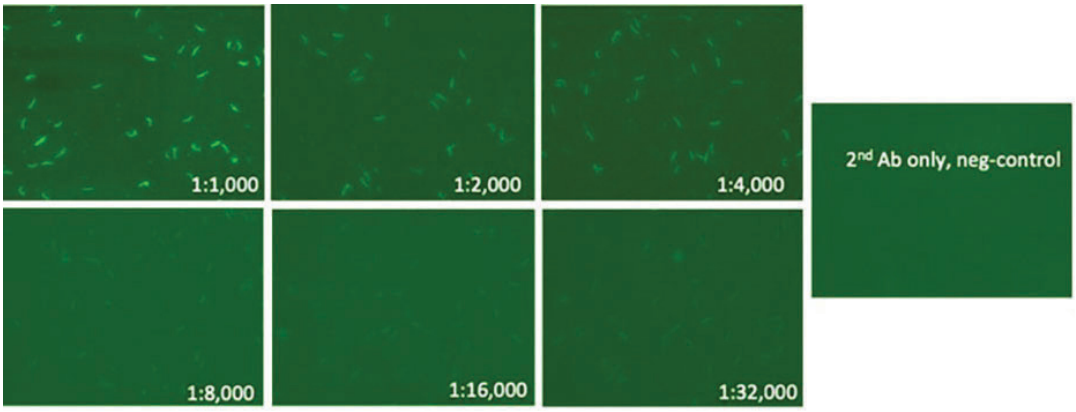
Antibody titer after 2nd immunization

	3D7-PP	3D7-His	3D7-GST
Mouse-1	**25600**	800	400
Mouse-2	**51200**	<100	400
Mouse-3	**25600**	400	400
Mouse-4	**25600**	<100	800

Antibody titer after 3rd immunization

	3D7-PP	3D7-His	3D7-GST
Mouse-1	**201400**	25600	12800
Mouse-2	**402800**	12800	12800
Mouse-3	**201400**	25600	12800
Mouse-4	**402800**	12800	12800

Figure 11. IFA of plasmodium sporozoites (3D7) stained with anti-P_{24} particle presenting the small domain of the CS protein mouse sera



Development

We anticipate conducting an animal challenge study for BWV-302 in the first half of 2022. Upon completion, the technology will be transferred to a partner CDMO for process optimization, GMP production and toxicology studies, as well as other studies required by the FDA for IND submission, currently anticipated for the second half of 2022. Following IND submission immediately upon completion of the toxicology study, if successful, we intend to initiate our Phase I clinical trial in healthy adults ages 18 to 54 upon acceptance by the FDA, which we anticipate to occur in first half of 2023.

Government Regulation and Product Approval

The FDA and other regulatory authorities at federal, state and local levels, as well as in foreign countries, extensively regulate, among other things, the research, development, testing, manufacture, quality control, import, export, safety, effectiveness, labeling, packaging, storage, distribution, record keeping, approval, advertising, promotion, marketing, post-approval monitoring and post-approval reporting of drugs and biologics such as those we are developing.

Small molecule drugs are subject to regulation under the Food, Drug, and Cosmetic Act, or FDCA, and biological products are additionally subject to regulation under the Public Health Service Act, or PHSA, and both are subject to additional federal, state, local and foreign statutes and regulations. We, along with third-party contractors, will be required to navigate the various preclinical, clinical and commercial approval requirements of the governing regulatory agencies of the countries in which we wish to conduct studies or seek approval or licensure of our product candidates.

United States

U. S. Biopharmaceuticals Regulation

The process required by the FDA before drug and biologic product candidates may be marketed in the United States generally involves the following:

- completion of extensive preclinical laboratory tests and animal studies performed in accordance with applicable regulations, including the FDA's Good Laboratory Practice, or GLP, regulations;
- submission to the FDA of an investigational new drug application, IND, which must become effective before clinical trials may begin;
- approval by an independent institutional review board or ethics committee at each clinical site before the trial is commenced;
- performance of adequate and well-controlled human clinical trials in accordance with FDA's Good Clinical Practice, or GCP, regulations to establish the safety and efficacy of a drug candidate and safety, purity and potency of a proposed biologic product candidate for its intended purpose;
- preparation of and submission to the FDA of a new drug application, or NDA, or biologics license application, or BLA, as applicable, after completion of all pivotal clinical trials;
- satisfactory completion of an FDA Advisory Committee review, if applicable;
- a determination by the FDA within 60 days of its receipt of an NDA or BLA to file the application for review;
- satisfactory completion of an FDA pre-approval inspection of the manufacturing facility or facilities at which the proposed product is produced to assess compliance with current Good Manufacturing Practice requirements, or cGMPs, and of selected clinical investigation sites to assess compliance with GCPs; and
- FDA review and approval of an NDA, or licensure of a BLA, to permit commercial marketing of the product for particular indications for use in the United States.

Preclinical and Clinical Development

Prior to beginning the first clinical trial with a product candidate, we must submit an IND to the FDA. An IND is a request for authorization from the FDA to administer an investigational new drug product to humans. The central focus of an IND submission is on the general investigational plan and the protocol or protocols for preclinical studies and clinical trials. The IND also includes results of animal and in vitro studies assessing the toxicology, pharmacokinetics, pharmacology and harmacodynamics characteristics of the product, chemistry, manufacturing and controls information, and any available human data or literature to support the use of the investigational product. An IND must become effective before human clinical trials may begin. The IND automatically becomes effective 30 days after receipt by the FDA, unless the FDA, within the 30-day period, raises safety concerns or questions about the proposed clinical trial. In such a case, the IND may be placed on clinical hold and the IND sponsor and the FDA must resolve any outstanding concerns or questions before the clinical trial can begin. Submission of an IND therefore may or may not result in FDA authorization to begin a clinical trial.

Clinical trials involve the administration of the investigational product to human subjects under the supervision of qualified investigators in accordance with GCPs, which include the requirement that all research subjects provide their informed consent for their participation in any clinical study. Clinical trials are conducted under protocols detailing, among other things, the objectives of the study, the parameters to be used in monitoring safety and the effectiveness criteria to be evaluated. A separate submission to the existing IND must be made for each successive clinical trial conducted during product development and for any subsequent protocol amendments. Furthermore, an independent institutional review board for each site proposing to conduct the clinical trial must review and approve the plan for any clinical trial and its informed consent form before the clinical trial begins at that site, and must monitor the study until completed. Regulatory authorities, the institutional review board or the sponsor may suspend a clinical trial at any time on various grounds, including a finding that the subjects are being exposed to an unacceptable health risk or that the trial is unlikely to meet its stated objectives. Some studies also include oversight by an independent group of qualified experts organized by the clinical study sponsor, known as a data safety monitoring board, which provides authorization for whether or not a study may move forward at designated check points based on access to certain data from the study and may halt the clinical trial if it determines that there is an unacceptable safety risk for subjects or other grounds, such as no demonstration of efficacy.

For purposes of biopharmaceutical development, human clinical trials are typically conducted in three sequential phases that may overlap or be combined;

- *Phase 1.* The investigational product is initially introduced into patients with the target disease or condition. These studies are designed to test the safety, dosage tolerance, absorption, metabolism and distribution of the investigational product in humans, the side effects associated with increasing doses, and, if possible, to gain early evidence on effectiveness.
- *Phase 2.* The investigational product is administered to a limited patient population to evaluate the preliminary efficacy, optimal dosages and dosing schedule and to identify possible adverse side effects and safety risks.
- *Phase 3.* The investigational product is administered to an expanded patient population to further evaluate dosage, to provide statistically significant evidence of clinical efficacy and to further test for safety, generally at multiple geographically dispersed clinical trial sites. These clinical trials are intended to establish the overall risk/benefit ratio of the investigational product and to provide an adequate basis for product approval.

In some cases, the FDA may require, or companies may voluntarily pursue, additional clinical trials after a product is approved to gain more information about the product. These so-called Phase 4 studies may be made a condition to approval of the application. Concurrent with clinical trials, companies may complete additional animal studies and develop additional information about the characteristics of the product candidate and must finalize a process for manufacturing the product in commercial quantities in accordance with cGMP requirements. The manufacturing process must be capable of consistently producing quality batches of the product candidate and, among other things, must develop methods for testing the identity, strength, quality and purity of the final product, or for biologics, the safety, purity and potency. Additionally, appropriate packaging must be selected and tested and stability studies must be conducted to demonstrate that the product candidate does not undergo unacceptable deterioration over its shelf life.

During all phases of clinical development, regulatory agencies require extensive monitoring and auditing of all clinical activities, clinical data, and clinical study investigators. The FDA or the sponsor or its data safety monitoring board may suspend a clinical study at any time on various grounds, including a finding that the research patients or patients are being exposed to an unacceptable health risk. Similarly, an institutional review board can suspend or terminate approval of a clinical study at its institution if the clinical study is not being conducted in accordance with the institutional review board's requirements or if the biological product candidate has been associated with unexpected serious harm to patients. There are also requirements governing the reporting of ongoing clinical trials and completed clinical trial results to public registries. Sponsors of clinical trials of FDA-regulated products are required to register and disclose certain clinical trial information, which is publicly available at *www.clinicaltrials.gov*.

NDA/BLA Submission and Review

Assuming successful completion of all required testing in accordance with all applicable regulatory requirements, the results of product development, nonclinical studies and clinical trials are submitted to the FDA as part of an NDA or BLA, as applicable, requesting approval to market the product for one or more indications. The application must include all relevant data available from pertinent preclinical studies and clinical trials, including negative or ambiguous results as well as positive findings, together with detailed information relating to the product's chemistry, manufacturing, controls, and proposed labeling, among other things. The submission of an application requires payment of a substantial application user fee to the FDA, unless a waiver or exemption applies. The FDA has sixty days from the applicant's submission to either issue a refusal to file letter or accept the application for filing, indicating that it is sufficiently complete to permit substantive review.

Once an NDA or BLA has been accepted for filing, the FDA's goal is to review standard applications within 10 months after it accepts the application for filing, or, if the application qualifies for priority review, six months after the FDA accepts the application for filing. In both standard and priority reviews, the review process is often significantly extended by FDA requests for additional information or clarification. The FDA reviews an NDA to determine whether a drug is safe and effective for its intended use and a BLA to determine whether a biologic is safe, pure and potent. FDA also reviews whether the facility in which the product is manufactured, processed, packed or held meets standards designed to assure and preserve the product's identity, safety, strength, quality, potency and purity. The FDA may convene an advisory committee to provide clinical insight on application review questions. Before approving an NDA or BLA, the FDA will typically inspect the facility or facilities where the product is manufactured. The FDA will not approve an application unless it determines that the manufacturing processes and facilities are in compliance with cGMP requirements and adequate to assure consistent production of the product within required specifications. Additionally, before approving an application, the FDA will typically inspect one or more clinical sites to assure compliance with GCPs. If the FDA determines that the application, manufacturing process or manufacturing facilities are not acceptable, it will outline the deficiencies in the submission and often will request additional testing or information. Notwithstanding the submission of any requested additional information, the FDA ultimately may decide that the application does not satisfy the regulatory criteria for approval.

After the FDA evaluates an application and conducts inspections of manufacturing facilities where the investigational product and/or its drug substance will be manufactured, the FDA may issue an approval letter or a Complete Response letter. An approval letter authorizes commercial marketing of the product with specific prescribing information for specific indications. A Complete Response letter will describe all of the deficiencies that the FDA has identified in the application, except that where the FDA determines that the data supporting the application are inadequate to support approval, the FDA may issue the Complete Response letter without first conducting required inspections, testing submitted product lots and/or reviewing proposed labeling. In issuing the Complete Response letter, the FDA may recommend actions that the applicant might take to place the application in condition for approval, including requests for additional information or clarification, which may include the potential requirement for additional clinical studies. The FDA may delay or refuse approval of an application if applicable regulatory criteria are not satisfied, require additional testing or information and/or require post-marketing testing and surveillance to monitor safety or efficacy of a product.

If regulatory approval of a product is granted, such approval will be granted for particular indications and may entail limitations on the indicated uses for which such product may be marketed. For example, the FDA may approve the application with a risk evaluation and mitigation strategy, or REMS, to ensure the benefits of the product outweigh its risks. A REMS is a safety strategy to manage a known or potential serious risk associated with a product and to enable patients to have continued access to such medicines by managing their safe use, and could include medication guides, physician communication plans, or elements to assure safe use, such as restricted

distribution methods, patient registries and other risk minimization tools. The FDA also may condition approval on, among other things, changes to proposed labeling or the development of adequate controls and specifications. Once approved, the FDA may withdraw the product approval if compliance with pre- and post-marketing requirements is not maintained or if problems occur after the product reaches the marketplace. The FDA may require one or more Phase 4 post-market studies and surveillance to further assess and monitor the product's safety and effectiveness after commercialization, and may limit further marketing of the product based on the results of these post-marketing studies.

Expedited Development and Review Programs

The FDA offers a number of expedited development and review programs for qualifying product candidates. The fast track program is intended to expedite or facilitate the process for reviewing new products that meet certain criteria. Specifically, new products are eligible for fast track designation if they are intended to treat a serious or life-threatening disease or condition and demonstrate the potential to address unmet medical needs for the disease or condition. Fast track designation applies to the combination of the product and the specific indication for which it is being studied. The sponsor of a fast track product has opportunities for frequent interactions with the review team during product development and, once an NDA or BLA is submitted, the product may be eligible for priority review. A fast track product may also be eligible for rolling review, where the FDA may consider for review sections of the NDA or BLA on a rolling basis before the complete application is submitted, if the sponsor provides a schedule for the submission of the sections of the application, the FDA agrees to accept sections of the application and determines that the schedule is acceptable, and the sponsor pays any required user fees upon submission of the first section of the application.

A product intended to treat a serious or life-threatening disease or condition may also be eligible for breakthrough therapy designation to expedite its development and review. A product can receive breakthrough therapy designation if preliminary clinical evidence indicates that the product, alone or in combination with one or more other drugs or biologics, may demonstrate substantial improvement over existing therapies on one or more clinically significant endpoints, such as substantial treatment effects observed early in clinical development. The designation includes all of the fast track program features, as well as more intensive FDA interaction and guidance beginning as early as Phase 1 and an organizational commitment to expedite the development and review of the product, including involvement of senior managers.

Any marketing application for a drug or biologic submitted to the FDA for approval, including a product with a fast track designation and/or breakthrough therapy designation, may be eligible for other types of FDA programs intended to expedite the FDA review and approval process, such as priority review and accelerated approval. A product is eligible for priority review if it has the potential to provide a significant improvement in the treatment, diagnosis or prevention of a serious disease or condition. Priority review designation means the FDA's goal is to take action on the marketing application within six months of the 60-day filing date.

Additionally, products studied for their safety and effectiveness in treating serious or life-threatening diseases or conditions may receive accelerated approval upon a determination that the product has an effect on a surrogate endpoint that is reasonably likely to predict clinical benefit, or on a clinical endpoint that can be measured earlier than irreversible morbidity or mortality, that is reasonably likely to predict an effect on irreversible morbidity or mortality or other clinical benefit, taking into account the severity, rarity, or prevalence of the condition and the availability or lack of alternative treatments. As a condition of accelerated approval, the FDA will generally require the sponsor to perform adequate and well-controlled post-marketing clinical studies to verify and describe the anticipated effect on irreversible morbidity or mortality or other clinical benefit. In addition, the FDA currently requires as a condition for accelerated approval pre-approval of promotional materials, which could adversely impact the timing of the commercial launch of the product.

Fast track designation, breakthrough therapy designation and priority review do not change the standards for approval but may expedite the development or approval process. Even if a product qualifies for one or more of these programs, the FDA may later decide that the product no longer meets the conditions for qualification or decide that the time period for FDA review or approval will not be shortened.

Orphan Drug Designation

Under the Orphan Drug Act, the FDA may grant orphan designation to a drug or biologic intended to treat a rare disease or condition, which is a disease or condition that affects fewer than 200,000 individuals in the United States, or more than 200,000 individuals in the United States for which there is no reasonable expectation that the cost of developing and making available in the United States a drug or biologic for this type of disease or condition will be recovered from sales in the United States for that drug or biologic. Orphan drug designation must be requested before submitting an NDA or BLA. After the FDA grants orphan drug designation, the generic identity of the therapeutic agent and its potential orphan use are disclosed publicly by the FDA. The orphan drug designation does not convey any advantage in, or shorten the duration of, the regulatory review or approval process.

If a product that has orphan drug designation subsequently receives the first FDA approval for the disease for which it has such designation, the product is entitled to orphan drug exclusive approval (or exclusivity), which means that the FDA may not approve any other applications, including a full NDA or BLA, to market the same drug or biologic for the same indication for seven years, except in limited circumstances, such as a showing of clinical superiority to the product with orphan drug exclusivity or if the FDA finds that the holder of the orphan drug exclusivity has not shown that it can assure the availability of sufficient quantities of the orphan drug to meet the needs of patients with the disease or condition for which the drug was designated. Orphan drug exclusivity does not prevent the FDA from approving a different drug or biologic for the same disease or condition, or the same drug or biologic for a different disease or condition. Among the other benefits of orphan drug designation are tax credits for certain research and a waiver of the NDA or BLA application fee.

A designated orphan drug may not receive orphan drug exclusivity if it is approved for a use that is broader than the indication for which it received orphan designation. In addition, exclusive marketing rights in the United States may be lost if the FDA later determines that the request for designation was materially defective.

Post-Approval Requirements

Any products manufactured or distributed by us pursuant to FDA approvals are subject to pervasive and continuing regulation by the FDA, including, among other things, requirements relating to record-keeping, reporting of adverse experiences, periodic reporting, product sampling and distribution, and advertising and promotion of the product. After approval, most changes to the approved product, such as adding new indications or other labeling claims, are subject to prior FDA review and approval. There also are continuing user fee requirements, under which the FDA assesses an annual program fee for each product identified in an approved NDA or BLA. Biopharmaceutical manufacturers and their subcontractors are required to register their establishments with the FDA and certain state agencies, and are subject to periodic unannounced inspections by the FDA and certain state agencies for compliance with cGMPs, which impose certain procedural and documentation requirements upon us and our third-party manufacturers. Changes to the manufacturing process are strictly regulated, and, depending on the significance of the change, may require prior FDA approval before being implemented. FDA regulations also require investigation and correction of any deviations from cGMPs and impose reporting requirements upon us and any third-party manufacturers that we may decide to use. Accordingly, manufacturers must continue to expend time, money and effort in the area of production and quality control to maintain compliance with cGMPs and other aspects of regulatory compliance.

The FDA may withdraw approval if compliance with regulatory requirements and standards is not maintained or if problems occur after the product reaches the market. Later discovery of previously unknown problems with a product, including adverse events of unanticipated severity or frequency, or with manufacturing processes, or failure to comply with regulatory requirements, may result in revisions to the approved labeling to add new safety information; imposition of post-market studies or clinical studies to assess new safety risks; or imposition of distribution restrictions or other restrictions under a REMS program. Other potential consequences include, among other things:

- restrictions on the marketing or manufacturing of a product, complete withdrawal of the product from the market or product recalls;
- fines, warning or untitled letters or holds on post-approval clinical studies;

- refusal of the FDA to approve pending applications or supplements to approved applications, or suspension or revocation of existing product approvals;
- product seizure or detention, or refusal of the FDA to permit the import or export of products;
- consent decrees, corporate integrity agreements, debarment or exclusion from federal healthcare programs;
- mandated modification of promotional materials and labeling and the issuance of corrective information;
- the issuance of safety alerts, Dear Healthcare Provider letters, press releases and other communications containing warnings or other safety information about the product; or
- injunctions or the imposition of civil or criminal penalties.

The FDA closely regulates the marketing, labeling, advertising and promotion of biopharmaceutical products. A company can make only those claims relating to safety and efficacy, purity and potency that are approved by the FDA and in accordance with the provisions of the approved label. However, companies may share truthful and not misleading information that is otherwise consistent with a product's FDA approved labeling. The FDA and other agencies actively enforce the laws and regulations prohibiting the promotion of off-label uses. Failure to comply with these requirements can result in, among other things, adverse publicity, warning letters, corrective advertising and potential civil and criminal penalties. Physicians may prescribe legally available products for uses that are not described in the product's labeling and that differ from those tested by us and approved by the FDA. Such off-label uses are common across medical specialties. Physicians may believe that such off-label uses are the best treatment for many patients in varied circumstances. The FDA does not regulate the behavior of physicians in their choice of treatments. The FDA does, however, restrict manufacturer's communications on the subject of off-label use of their products.

U.S. Market Exclusivity

A biological product can obtain pediatric market exclusivity in the U.S., which, if granted, adds six months to existing exclusivity periods, including some regulatory exclusivity periods tied to patent terms. This six-month exclusivity, which runs from the end of other exclusivity protection or patent term, may be granted based on the voluntary completion of a pediatric study in accordance with an FDA-issued "Written Request" for such a study.

The Biologics Price Competition and Innovation Act of 2009, or BPCIA, created an abbreviated approval pathway for biological products shown to be biosimilar to, or interchangeable with, an FDA-licensed reference biological product. This amendment to the PHSA attempts to minimize duplicative testing.

Biosimilarity, which requires that there be no clinically meaningful differences between the biological product and the reference product in terms of safety, purity, and potency, can be shown through analytical studies, animal studies, and a clinical trial or trials. Interchangeability requires that a product is biosimilar to the reference product and the product must demonstrate that it can be expected to produce the same clinical results as the reference product and, for products administered multiple times, the biologic and the reference biologic may be interchanged after one has been previously administered without increasing safety risks or risks of diminished efficacy relative to exclusive use of the reference biologic. However, complexities associated with the larger, and often more complex, structure of biological products, as well as the process by which such products are manufactured, pose significant hurdles to implementation that are still being worked out by the FDA.

The FDA will not accept an application for a biosimilar or interchangeable product based on the reference biological product until four years after the date of first licensure of the reference product, and the FDA will not approve an application for a biosimilar or interchangeable product based on the reference biological product until 12 years after the date of first licensure of the reference product. "First licensure" typically means the initial date the particular product at issue was licensed in the U.S. Date of first licensure does not include the date of licensure of (and a new period of exclusivity is not available for) a biological product if the licensure is for a supplement for the biological product or for a subsequent application by the same sponsor or manufacturer of the biological product (or licensor, predecessor in interest, or other related entity) for a change (not including a modification to the structure

of the biological product) that results in a new indication, route of administration, dosing schedule, dosage form, delivery system, delivery device or strength, or for a modification to the structure of the biological product that does not result in a change in safety, purity, or potency.

The BPCIA is complex and continues to be interpreted and implemented by the FDA. In addition, government proposals have sought to reduce the 12-year reference product exclusivity period. Other aspects of the BPCIA, some of which may impact the BPCIA exclusivity provisions, have also been the subject of recent litigation. As a result, the ultimate implementation and impact of the BPCIA is subject to significant uncertainty.

Pediatric Study Plan and Pediatric Exclusivity

Under the Pediatric Research Equity Act, as amended, or the PREA, certain NDAs and certain NDA supplements must contain data that can be used to assess the safety and efficacy of the product candidate for the claimed indications in all relevant pediatric subpopulations and to support dosing and administration for each pediatric subpopulation for which the product is safe and effective. The FDA may grant deferrals for submission of pediatric data or full or partial waivers. The PREA requires that a sponsor who is planning to submit a marketing application for a product candidate that includes a new active ingredient, new indication, new dosage form, new dosing regimen or new route of administration submit an initial Pediatric Study Plan, or the PSP, within 60 days of an end-of-phase 2 meeting or, if there is no such meeting, as early as practicable before the initiation of the phase 3 or phase 2/3 study. The initial PSP must include an outline of the pediatric study or studies that the sponsor plans to conduct, including study objectives and design, age groups, relevant endpoints and statistical approach, or a justification for not including such detailed information, and any request for a deferral of pediatric assessments or a full or partial waiver of the requirement to provide data from pediatric studies along with supporting information. The FDA and the sponsor must reach an agreement on the PSP. A sponsor can submit amendments to an agreed-upon initial PSP at any time if changes to the pediatric plan need to be considered based on data collected from preclinical studies, early phase clinical trials and/or other clinical development programs. Unless otherwise required by regulation, the PREA does not apply to a drug for an indication for which orphan designation has been granted, except that the PREA will apply to an original NDA for a new active ingredient that is orphan-designated if the drug is a molecularly targeted cancer product intended for the treatment of an adult cancer and is directed at a molecular target that the FDA determines to be substantially relevant to the growth or progression of a pediatric cancer.

A drug can also obtain pediatric market exclusivity in the United States. Pediatric exclusivity, if granted, adds six months to existing exclusivity periods and patent terms. This six-month exclusivity, which runs from the end of other exclusivity protection or patent term, may be granted based on the voluntary completion of a pediatric study in accordance with an FDA-issued “Written Request” for such a study.

Patent Term Restoration and Extension

Depending upon the timing, duration and specifics of the FDA approval of our product candidates, some of our U.S. patents may be eligible for limited patent term extension. The provisions of the Drug Price Competition and Patent Term Restoration Act, informally known as the Hatch-Waxman Act, permit a patent restoration term of up to five years as compensation for patent term lost during product development and the FDA regulatory review process. However, patent term restoration cannot extend the remaining term of a patent beyond a total of 14 years from the product’s approval date. The patent term restoration period is generally one-half the time between the effective date of an IND and the submission date of a BLA plus the time between the submission date of a BLA and the approval of that application. Only one patent applicable to an approved product is eligible for the extension and the application for the extension must be submitted prior to the expiration of the patent. The USPTO, in consultation with the FDA, reviews and approves the application for any patent term extension or restoration. In the future, we may apply for restoration of patent term for one of our currently owned or licensed patents to add patent life beyond its current expiration date, depending on the expected length of the clinical trials and other factors involved in the filing of the relevant BLA.

Many other countries also provide for patent term extensions or similar extensions of patent protection for biologic products. For example, in Japan, it may be possible to extend the patent term for up to five years and in Europe, it may be possible to obtain a supplementary patent certificate that would effectively extend patent protection for up to five years.

Federal and State Fraud and Abuse, Data Privacy and Security, and Transparency Laws and Regulations

In addition to FDA restrictions on marketing of pharmaceutical products, federal and state healthcare laws and regulations restrict business practices in the biopharmaceutical industry. These laws may impact, among other things, our current and future business operations, including our clinical research activities, and proposed sales, marketing and education programs and constrain the business or financial arrangements and relationships with healthcare providers and other parties through which we market, sell and distribute our products for which we obtain marketing approval. These laws include anti-kickback and false claims laws and regulations, data privacy and security, and transparency laws and regulations, including, without limitation, those laws described below.

The U.S. federal Anti-Kickback Statute prohibits any person or entity from, among other things, knowingly and willfully offering, paying, soliciting or receiving remuneration to induce or in return for purchasing, leasing, ordering or arranging for or recommending the purchase, lease or order of any item or service reimbursable under Medicare, Medicaid or other federal healthcare programs. The term "remuneration" has been broadly interpreted to include anything of value. The U.S. federal Anti-Kickback Statute has been interpreted to apply to arrangements between pharmaceutical manufacturers on the one hand and prescribers, purchasers and formulary managers on the other. Although there are a number of statutory exceptions and regulatory safe harbors protecting some common activities from prosecution, the exceptions and safe harbors are drawn narrowly. Practices that involve remuneration that may be alleged to be intended to induce prescribing, purchases or recommendations may be subject to scrutiny if they do not qualify for an exception or safe harbor. Several courts have interpreted the statute's intent requirement to mean that if any one purpose of an arrangement involving remuneration is to induce referrals of federal healthcare covered business, the statute has been violated.

A person or entity does not need to have actual knowledge of this statute or specific intent to violate it in order to have committed a violation. In addition, the government may assert that a claim including items or services resulting from a violation of the U.S. federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the federal civil False Claims Act or the civil monetary penalties laws.

Federal civil and criminal false claims laws and civil monetary penalties laws, including the federal civil False Claims Act, which can be enforced by individuals through civil whistleblower and qui tam actions, prohibit any person or entity from, among other things, knowingly presenting, or causing to be presented, a false claim for payment to the federal government or knowingly making, using or causing to be made or used a false record or statement material to a false or fraudulent claim to the federal government. A claim includes "any request or demand" for money or property presented to the U.S. government. Several pharmaceutical and other healthcare companies have been prosecuted under these laws for allegedly providing free product to customers with the expectation that the customers would bill federal programs for the product. Other companies have been prosecuted for causing false claims to be submitted because of the companies' marketing of products for unapproved, and thus non-reimbursable, uses.

The federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, created additional federal criminal statutes that prohibit, among other things, knowingly and willfully executing a scheme to defraud any healthcare benefit program, including private third-party payors and knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false, fictitious or fraudulent statement in connection with the delivery of or payment for healthcare benefits, items or services. Also, many states have similar fraud and abuse statutes or regulations that apply to items and services reimbursed under Medicaid and other state programs, or, in several states, apply regardless of the payor.

In addition, we may be subject to data privacy and security regulation by both the federal government and the states in which we conduct our business. HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act, or HITECH, and their respective implementing regulations, impose specified requirements on certain types of individuals and entities relating to the privacy, security and transmission of individually identifiable health information. Among other things, HITECH makes HIPAA's security standards directly applicable to "business associates," defined as independent contractors or agents of covered entities, which include certain healthcare providers, healthcare clearinghouses and health plans, that create, receive, maintain or transmit individually identifiable health information in connection with providing a service for or on behalf of a covered entity. HITECH also increased the civil and criminal penalties that may be imposed against covered entities, business associates and possibly other persons, and gave state attorneys general new authority to file civil actions for damages or injunctions in federal courts to enforce HIPAA and seek attorney's fees and costs associated with pursuing federal

civil actions. In addition, state laws govern the privacy and security of health information in certain circumstances, many of which are not pre-empted by HIPAA, differ from each other in significant ways and may not have the same effect, thus complicating compliance efforts.

The federal Physician Payments Sunshine Act requires certain manufacturers of drugs, devices, biologics and medical supplies for which payment is available under Medicare, Medicaid or the Children's Health Insurance Program, with specific exceptions, to report annually to the Centers for Medicare & Medicaid Services, or CMS, information related to payments or other transfers of value made to physicians and teaching hospitals, and applicable manufacturers and applicable group purchasing organizations to report annually to CMS ownership and investment interests held by physicians and their immediate family members.

We may also be subject to state laws that require pharmaceutical companies to comply with the pharmaceutical industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government, state laws that require drug manufacturers to report information related to payments and other transfers of value to physicians and other healthcare providers, marketing expenditures or drug pricing, and state and local laws that require the registration of pharmaceutical sales representatives.

Because of the breadth of these laws and the narrowness of available statutory exceptions and regulatory safe harbors, it is possible that some of our business activities could be subject to challenge under one or more of such laws. If our operations are found to be in violation of any of the federal and state laws described above or any other governmental regulations that apply to us, we may be subject to significant criminal, civil and administrative penalties including damages, fines, imprisonment, disgorgement, additional reporting requirements and oversight if we become subject to a corporate integrity agreement or similar agreement to resolve allegations of non-compliance with these laws, contractual damages, reputational harm, diminished profits and future earnings, disgorgement, exclusion from participation in government healthcare programs and the curtailment or restructuring of our operations, any of which could adversely affect our ability to operate our business and our results of operations. To the extent that any of our products are sold in a foreign country, we may be subject to similar foreign laws and regulations, which may include, for instance, applicable post-marketing requirements, including safety surveillance, anti-fraud and abuse laws, implementation of corporate compliance programs, reporting of payments or transfers of value to healthcare professionals, and additional data privacy and security requirements.

Healthcare Reform

Coverage and Reimbursement

The future commercial success of our product candidates, if approved, will depend in part on the extent to which third-party payors, such as governmental payor programs at the federal and state levels, including Medicare and Medicaid, private health insurers and other third-party payors, provide coverage of and establish adequate reimbursement levels for our product candidates. Third-party payors generally decide which products they will pay for and establish reimbursement levels for those products. In particular, in the United States, no uniform policy for coverage and reimbursement exists. Private health insurers and other third-party payors often provide coverage and reimbursement for products based on the level at which the government, through the Medicare program, provides coverage and reimbursement for such products, but also on their own methods and approval process apart from Medicare determinations. Therefore, coverage and reimbursement can differ significantly from payor to payor.

In the United States, the European Union, or EU, and other potentially significant markets for our product candidates, government authorities and third-party payors are increasingly attempting to limit or regulate the price of products, particularly for new and innovative products, which often has resulted in average selling prices lower than they would otherwise be. Further, the increased emphasis on managed healthcare in the United States and on country and regional pricing and reimbursement controls in the EU will put additional pressure on product pricing, reimbursement and usage. These pressures can arise from rules and practices of managed care groups, judicial decisions and laws and regulations related to Medicare, Medicaid and healthcare reform, pharmaceutical coverage and reimbursement policies and pricing in general.

Third-party payors are increasingly imposing additional requirements and restrictions on coverage and limiting reimbursement levels for products. For example, federal and state governments reimburse products at varying rates generally below average wholesale price. These restrictions and limitations influence the purchase of products. Third-party payors may limit coverage to specific products on an approved list, or formulary, which

might not include all of the FDA-approved products for a particular indication. Similarly, because certain of our product candidates are physician-administered, separate reimbursement for the product itself may or may not be available. Instead, the administering physician may only be reimbursed for providing the treatment or procedure in which our product is used. Third-party payors are increasingly challenging the price and examining the medical necessity and cost-effectiveness of products, in addition to their safety and efficacy. We may need to conduct expensive pharmacoeconomic studies in order to demonstrate the medical necessity and cost-effectiveness of our product candidates, in addition to the costs required to obtain the FDA approvals. Our product candidates may not be considered medically necessary or cost-effective. A payor's decision to provide coverage for a product does not imply that an adequate reimbursement rate will be approved. Adequate third-party payor reimbursement may not be available to enable us to realize an appropriate return on our investment in product development. Legislative proposals to reform healthcare or reduce costs under government insurance programs may result in lower reimbursement for our product candidates, if approved, or exclusion of our product candidates from coverage and reimbursement. The cost containment measures that third-party payors and providers are instituting and any healthcare reform could significantly reduce our revenue from the sale of any approved product candidates.

The United States and some foreign jurisdictions are considering enacting or have enacted a number of additional legislative and regulatory proposals to change the healthcare system in ways that could affect our ability to sell our product candidates profitably, if approved. Among policy makers and payors in the United States and elsewhere, there is significant interest in promoting changes in healthcare systems with the stated goals of containing healthcare costs, improving quality and expanding access. In the United States, the pharmaceutical industry has been a particular focus of these efforts, which include major legislative initiatives to reduce the cost of care through changes in the healthcare system, including limits on the pricing, coverage, and reimbursement of pharmaceutical and biopharmaceutical products, especially under government-funded healthcare programs, and increased governmental control of drug pricing.

There have been several U.S. government initiatives over the past few years to fund and incentivize certain comparative effectiveness research, including creation of the Patient-Centered Outcomes Research Institute under the ACA. It is also possible that comparative effectiveness research demonstrating benefits in a competitor's product could adversely affect the sales of our product candidates.

The ACA became law in March 2010 and substantially changed the way healthcare is financed by third-party payors, and significantly impacts the U.S. pharmaceutical industry. Among other measures that may have an impact on our business, the ACA established an annual, nondeductible fee on any entity that manufactures or imports specified branded prescription drugs and biologic agents; a new Medicare Part D coverage gap discount program; and a new formula that increased the rebates a manufacturer must pay under the Medicaid Drug Rebate Program. Additionally, the ACA extended manufacturers' Medicaid rebate liability, expands eligibility criteria for Medicaid programs, and expanded entities eligible for discounts under the Public Health Service Act. At this time, we are unsure of the full impact that the ACA will have on our business.

Since its enactment, there have been judicial and Congressional challenges to certain aspects of the ACA, as well as recent efforts by the Trump administration to repeal or replace certain aspects of the ACA, and we expect such challenges and amendments to continue. Since January 2017, President Trump has signed two Executive Orders and other directives designed to delay the implementation of certain ACA provisions or otherwise circumvent requirements for health insurance mandated by the ACA. Concurrently, Congress has considered legislation that would repeal or repeal and replace all or part of the ACA. While Congress has not passed comprehensive repeal legislation, two bills affecting the implementation of certain taxes under the ACA have been signed into law. The Tax Cuts and Jobs Act of 2017, or Tax Act, includes a provision that repealed, effective January 1, 2019, the tax-based shared responsibility payment imposed by the ACA on certain individuals who fail to maintain qualifying health coverage for all or part of a year that is commonly referred to as the "individual mandate." On January 22, 2018, President Trump signed a continuing resolution on appropriations for fiscal year 2018 that delayed the implementation of certain ACA-mandated fees, including the so-called "Cadillac" tax on certain high cost employer-sponsored insurance plans, the annual fee imposed on certain health insurance providers based on market share, and the medical device excise tax on nonexempt medical devices. The Bipartisan Budget Act of 2018, or the BBA, among other things, amended the ACA, effective January 1, 2019, to increase from 50% to 70% the point-of-sale discount that is owed by pharmaceutical manufacturers who participate in Medicare Part D and to

close the coverage gap in most Medicare drug plans, commonly referred to as the “donut hole.” In July 2018, CMS published a final rule permitting further collections and payments to and from certain ACA qualified health plans and health insurance issuers under the ACA adjustment program in response to the outcome of federal district court litigation regarding the method CMS uses to determine this risk adjustment. In December 2018, a U.S. District Court Judge in the Northern District of Texas, or Texas District Court Judge, ruled that the individual mandate is a critical and inseverable feature of the ACA, and therefore, because it was repealed as part of the Tax Act, the remaining provisions of the ACA are invalid as well. While the Texas District Court Judge, as well as the Trump administration and CMS, have stated that the ruling will have no immediate effect, it is unclear how this decision, subsequent appeals, and other efforts to repeal and replace the ACA will impact the ACA.

In addition, other legislative changes have been proposed and adopted since the ACA was enacted. In August 2011, the President signed into law the Budget Control Act of 2011, as amended, which, among other things, included aggregate reductions to Medicare payments to providers of 2% per fiscal year, which began in 2013 and, following passage of subsequent legislation, including the BBA, will continue through 2027 unless additional Congressional action is taken. In January 2013, the American Taxpayer Relief Act of 2012 was enacted which, among other things, reduced Medicare payments to several types of providers and increased the statute of limitations period for the government to recover overpayments to providers from three to five years.

Further, there has been increasing legislative and enforcement interest in the United States with respect to drug pricing practices. Specifically, there have been several recent U.S. Congressional inquiries and proposed and enacted federal and state legislation designed to, among other things, bring more transparency to drug pricing, review the relationship between pricing and manufacturer patient programs, and reform government program reimbursement methodologies for drugs. At the federal level, the Trump administration’s budget proposal for fiscal year 2019 contains further drug price control measures that could be enacted during the 2019 budget process or in other future legislation, including, for example, measures to permit Medicare Part D plans to negotiate the price of certain drugs under Medicare Part B, to allow some states to negotiate drug prices under Medicaid, and to eliminate cost sharing for generic drugs for low-income patients. Additionally, the Trump administration released a “Blueprint” to lower drug prices and reduce out of pocket costs of drugs that contains additional proposals to increase manufacturer competition, increase the negotiating power of certain federal healthcare programs, incentivize manufacturers to lower the list price of their products and reduce the out of pocket costs of drug products paid by consumers. The U.S. Department of Health and Human Services, or HHS, has already started the process of soliciting feedback on some of these measures and is implementing others under its existing authority. For example, in September 2018, CMS announced that it will allow Medicare Advantage plans the option to use step therapy for Part B drugs beginning January 1, 2019. On January 31, 2019, the HHS Office of Inspector General proposed modifications to U.S. federal Anti-Kickback Statute safe harbors which, among other things, may affect rebates paid by manufacturers to Medicare Part D plans, the purpose of which is to further reduce the cost of drug products to consumers. In addition, CMS issued a final rule, effective on July 9, 2019, that requires direct-to-consumer television advertisements of prescription drugs and biological products, for which payment is available through or under Medicare or Medicaid, to include in the advertisement the Wholesale Acquisition Cost, or list price, of that drug or biological product if it is equal to or greater than $35 for a monthly supply or usual course of treatment. Prescription drugs and biological products that are in violation of these requirements will be included on a public list. Congress and the Trump administration have each indicated that it will continue to seek new legislative and/or administrative measures to control drug costs. At the state level, legislatures have increasingly passed legislation and implemented regulations designed to control pharmaceutical and biological product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures, and, in some cases, designed to encourage importation from other countries and bulk purchasing. In addition, regional healthcare authorities and individual hospitals are increasingly using bidding procedures to determine which drugs and suppliers will be included in their healthcare programs. Furthermore, there has been increased interest by third party payors and governmental authorities in reference pricing systems and publication of discounts and list prices. These measures could reduce future demand for our products or put pressure on our pricing.

Additionally, in May 2018, the Trickett Wendler, Frank Mongiello, Jordan McLinn, and Matthew Bellina Right to Try Act of 2017, or the Right to Try Act, was signed into law. The law, among other things, provides a federal framework for certain patients to access certain investigational new drug products that have completed a Phase 1 clinical trial and that are undergoing investigation for FDA approval. Under certain circumstances, eligible

patients can seek treatment without enrolling in clinical trials and without obtaining FDA permission under the FDA expanded access program. There is no obligation for a drug manufacturer to make its drug products available to eligible patients as a result of the Right to Try Act.

Foreign Regulation

In order to market any product outside of the United States, we would need to comply with numerous and varying regulatory requirements of other countries regarding safety and efficacy and governing, among other things, clinical trials, marketing authorization, commercial sales and distribution of our product candidates. For example, in the EU, we must obtain authorization of a clinical trial application, or CTA, in each member state in which we intend to conduct a clinical trial. Whether or not we obtain FDA approval for a drug, we would need to obtain the necessary approvals by the comparable regulatory authorities of foreign countries before we can commence clinical trials or marketing of the drug in those countries. The approval process varies from country to country and can involve additional product testing and additional administrative review periods. The time required to obtain approval in other countries might differ from and be longer than that required to obtain FDA approval. Regulatory approval in one country does not ensure regulatory approval in another, but a failure or delay in obtaining regulatory approval in one country may negatively impact the regulatory process in others.

Further, some countries outside of the United States, including the EU member states, Switzerland and the United Kingdom, have also adopted data protection laws and regulations, which impose significant compliance obligations. In the EU, the collection and use of personal health data is governed by the provisions of the General Data Protection Regulation, or GDPR. The GDPR became effective on May 25, 2018, repealing its predecessor directive and increasing responsibility and liability of pharmaceutical companies in relation to the processing of personal data of EU subjects. The GDPR, together with the national legislation of the EU member states governing the processing of personal data, impose strict obligations and restrictions on the ability to process personal data, including health data from clinical trials and adverse event reporting. In particular, these obligations and restrictions concern potentially burdensome documentation requirements, granting certain rights to individuals to control how we collect, use, disclose, retain and process information about them, the information provided to the individuals, the transfer of personal data out of the EU, security breach notifications, and security and confidentiality of the personal data. The processing of sensitive personal data, such as physical health condition, may impose heightened compliance burdens under the GDPR and is a topic of active interest among foreign regulators. In addition, the GDPR provides for more robust regulatory enforcement and fines of up to €20 million or 4% of the annual global revenue of the noncompliant company, whichever is greater. Data protection authorities from the different EU member states may interpret the GDPR and national laws differently and impose additional requirements, which add to the complexity of processing personal data in the EU. Guidance on implementation and compliance practices are often updated or otherwise revised.

European Union

European Union Coverage Reimbursement and Pricing

In the European Union, pricing and reimbursement schemes vary widely from country to country. Some countries provide that drug products may be marketed only after a reimbursement price has been agreed. Some countries may require the completion of additional studies that compare the cost-effectiveness of a particular drug candidate to currently available therapies, or so called health technology assessments, in order to obtain reimbursement or pricing approval. For example, the European Union provides options for its member states to restrict the range of drug products for which their national health insurance systems provide reimbursement and to control the prices of medicinal products for human use. European Union member states may approve a specific price for a drug product or may instead adopt a system of direct or indirect controls on the profitability of the company.

EU Drug regulation

In order to market any product outside of the United States, we would need to comply with numerous and varying regulatory requirements of other countries and jurisdictions regarding quality, safety and efficacy and governing, among other things, clinical trials, marketing authorization, commercial sales and distribution of our products. Whether or not we obtain FDA approval for a product, we would need to obtain the necessary approvals by the comparable foreign regulatory authorities before we can commence clinical trials or marketing of the product

in foreign countries and jurisdictions such as in China and Japan. Although many of the issues discussed above with respect to the United States apply similarly in the context of the EU, the approval process varies between countries and jurisdictions and can involve additional product testing and additional administrative review periods. The time required to obtain approval in other countries and jurisdictions might differ from and be longer than that required to obtain FDA approval. Regulatory approval in one country or jurisdiction does not ensure regulatory approval in another, but a failure or delay in obtaining regulatory approval in one country or jurisdiction may negatively impact the regulatory process in others. Failure to comply with applicable foreign regulatory requirements, may be subject to, among other things, fines, suspension or withdrawal of regulatory approvals, product recalls, seizure of products, operating restrictions and criminal prosecution.

Non-clinical studies and clinical trials

Similarly to the United States, the various phases of non-clinical and clinical research in the EU are subject to significant regulatory controls.

Non-clinical studies are performed to demonstrate the health or environmental safety of new chemical or biological substances. Non-clinical studies must be conducted in compliance with the principles of good laboratory practice (GLP) as set forth in EU Directive 2004/10/EC. In particular, non-clinical studies, both in vitro and in vivo, must be planned, performed, monitored, recorded, reported and archived in accordance with the GLP principles, which define a set of rules and criteria for a quality system for the organizational process and the conditions for non-clinical studies. These GLP standards reflect the Organization for Economic Co-operation and Development requirements.

Clinical trials of medicinal products in the EU must be conducted in accordance with EU and national regulations and the International Conference on Harmonization (ICH) guidelines on good clinical practices (GCP) as well as the applicable regulatory requirements and the ethical principles that have their origin in the Declaration of Helsinki. Additional GCP guidelines from the European Commission, focusing in particular on traceability, apply to clinical trials of advanced therapy medicinal products. If the sponsor of the clinical trial is not established within the EU, it must appoint an entity within the EU to act as its legal representative. The sponsor must take out a clinical trial insurance policy, and in most EU member states, the sponsor is liable to provide ‘no fault’ compensation to any study subject injured in the clinical trial.

Certain countries outside of the United States, including the EU, have a similar process that requires the submission of a clinical study application (CTA) much like the IND prior to the commencement of human clinical studies. A CTA must be submitted to each country’s national health authority and an independent ethics committee, much like the FDA and the IRB, respectively. Once the CTA is approved by the national health authority and the ethics committee has granted a positive opinion in relation to the conduct of the trial in the relevant member state(s), in accordance with a country’s requirements, clinical study development may proceed.

The CTA must include, among other things, a copy of the trial protocol and an investigational medicinal product dossier containing information about the manufacture and quality of the medicinal product under investigation. Currently, CTAs must be submitted to the competent authority in each EU member state in which the trial will be conducted. Under the new Regulation on Clinical Trials, which is currently expected to become applicable by early 2022, there will be a centralized application procedure where one national authority takes the lead in reviewing the application and the other national authorities have only a limited involvement. Any substantial changes to the trial protocol or other information submitted with the CTA must be notified to or approved by the relevant competent authorities and ethics committees. Medicines used in clinical trials must be manufactured in accordance with good manufacturing practice (GMP). Other national and EU-wide regulatory requirements also apply.

Marketing Authorizations

To market a medicinal product in the EU and in many other foreign jurisdictions, we must obtain separate regulatory approvals. More concretely, in the EU, medicinal product candidates can only be commercialized after obtaining a Marketing Authorization (MA). To obtain regulatory approval of an investigational medicinal product under EU regulatory systems, we must submit a marketing authorization application (MAA.) The process for doing this depends, among other things, on the nature of the medicinal product. There are two types of MAs:

- the “Union MA”, which is issued by the European Commission through the Centralized Procedure, based on the opinion of the Committee for Medicinal Products for Human Use (CHMP) of the European Medicines Agency (EMA) and which is valid throughout the entire territory of the

EU. The Centralized Procedure is mandatory for certain types of products, such as (i) medicinal products derived from biotechnology medicinal products, (ii) designated orphan medicinal products, (iii) advanced therapy products (such as gene therapy, somatic cell therapy or tissue-engineered medicines), and (iv) medicinal products containing a new active substance indicated for the treatment certain diseases, such as HIV/AIDS, cancer, neurodegenerative diseases, diabetes, other auto-immune and viral diseases. The Centralized Procedure is optional for products containing a new active substance not yet authorized in the EU, or for products that constitute a significant therapeutic, scientific or technical innovation or that the granting of authorization would be in the interest of public health in the EU; and

- "National MAs", which are issued by the competent authorities of the EU member states and only cover their respective territory, are available for products not falling within the mandatory scope of the Centralized Procedure. Where a product has already been authorized for marketing in an EU member state, this National MA can be recognized in another member state through the Mutual Recognition Procedure. If the product has not received a National MA in any member state at the time of application, it can be approved simultaneously in various member states through the Decentralized Procedure. Under the Decentralized Procedure an identical dossier is submitted to the competent authorities of each of the member states in which the MA is sought, one of which is selected by the applicant as the Reference member state.

Under the above-described procedures, in order to grant the MA, the EMA or the competent authorities of the EU member states make an assessment of the risk-benefit balance of the product on the basis of scientific criteria concerning its quality, safety and efficacy.

Under the Centralized Procedure, the maximum timeframe for the evaluation of a MAA by the EMA is 210 days. Where there is a major public health interest and an unmet medical need for a product, the CHMP may perform an accelerated review of a MA in no more than 150 days (not including clock stops). Innovative products that target an unmet medical need and are expected to be of major public health interest may be eligible for a number of expedited development and review programs, such as the PRIME scheme, which provides incentives similar to the breakthrough therapy designation in the US PRIME is a voluntary scheme aimed at enhancing the EMA's support for the development of medicines that target unmet medical needs. It is based on increased interaction and early dialogue with companies developing promising medicines, to optimize their product development plans and speed up their evaluation to help them reach patients earlier. Product developers that benefit from PRIME designation can expect to be eligible for accelerated assessment but this is not guaranteed. The benefits of a PRIME designation include the appointment of a CHMP rapporteur before submission of a MAA, early dialogue and scientific advice at key development milestones, and the potential to qualify products for accelerated review earlier in the application process.

MAs have an initial duration of five years. After these five years, the authorization may be renewed for an unlimited period on the basis of a reevaluation of the risk-benefit balance, unless the EMA decides, on justified grounds relating to pharmacovigilance, to mandate one additional five-year renewal period.

Data and marketing exclusivity

The EU also provides opportunities for market exclusivity. Upon receiving MA, new chemical entity, or reference product candidates, generally receive eight years of data exclusivity and an additional two years of market exclusivity. If granted, the data exclusivity period prevents generic or biosimilar applicants from relying on the pre-clinical and clinical trial data contained in the dossier of the reference product when applying for a generic or biosimilar MA in the EU during a period of eight years from the date on which the reference product was first authorized in the EU. The market exclusivity period prevents a successful generic or biosimilar applicant from commercializing its product in the EU until 10 years have elapsed from the initial authorization of the reference product in the EU. The overall 10-year market exclusivity period can be extended to a maximum of eleven years if, during the first eight years of those 10 years, the MA holder obtains an authorization for one or more new therapeutic indications which, during the scientific evaluation prior to their authorization, are held to bring a significant clinical benefit in comparison with existing therapies. However, there is no guarantee that a product will be considered by the EU's regulatory authorities to be a new chemical entity, and products may not qualify for data exclusivity.

Pediatric Development

In the EU, MAAs for new medicinal products candidates have to include the results of trials conducted in the pediatric population, in compliance with a pediatric investigation plan (PIP) agreed with the EMA's Pediatric Committee (PDCO). The PIP sets out the timing and measures proposed to generate data to support a pediatric indication of the drug for which MA is being sought. The PDCO can grant a deferral of the obligation to implement some or all of the measures of the PIP until there are sufficient data to demonstrate the efficacy and safety of the product in adults. Further, the obligation to provide pediatric clinical trial data can be waived by the PDCO when these data is not needed or appropriate because the product is likely to be ineffective or unsafe in children, the disease or condition for which the product is intended occurs only in adult populations, or when the product does not represent a significant therapeutic benefit over existing treatments for pediatric patients. Once the MA is obtained in all EU Member States and study results are included in the product information, even when negative, the product is eligible for six months' supplementary protection certificate extension (if any is in effect at the time of authorization).

Post-Approval Requirements

Similar to the United States, both MA holders and manufacturers of medicinal products are subject to comprehensive regulatory oversight by the EMA, the European Commission and/or the competent regulatory authorities of the member states. The holder of a MA must establish and maintain a pharmacovigilance system and appoint an individual qualified person for pharmacovigilance who is responsible for oversight of that system. Key obligations include expedited reporting of suspected serious adverse reactions and submission of periodic safety update reports (PSURs).

All new MAA must include a risk management plan (RMP) describing the risk management system that the company will put in place and documenting measures to prevent or minimize the risks associated with the product. The regulatory authorities may also impose specific obligations as a condition of the MA. Such risk-minimization measures or post-authorization obligations may include additional safety monitoring, more frequent submission of PSURs, or the conduct of additional clinical trials or post-authorization safety studies.

The advertising and promotion of medicinal products is also subject to laws concerning promotion of medicinal products, interactions with physicians, misleading and comparative advertising and unfair commercial practices. All advertising and promotional activities for the product must be consistent with the approved summary of product characteristics, and therefore all off-label promotion is prohibited. Direct-to-consumer advertising of prescription medicines is also prohibited in the EU. Although general requirements for advertising and promotion of medicinal products are established under EU directives, the details are governed by regulations in each member state and can differ from one country to another.

The aforementioned EU rules are generally applicable in the European Economic Area (EEA) which consists of the 27 EU member states plus Norway, Liechtenstein and Iceland.

For other countries outside of the EU, such as countries in Latin America or Asia (e.g. China and Japan), the requirements governing the conduct of clinical studies, product licensing, pricing and reimbursement vary from country to country. In all cases, again, the clinical studies are conducted in accordance with GCP and the applicable regulatory requirements and the ethical principles that have their origin in the Declaration of Helsinki. If we fail to comply with applicable foreign regulatory requirements, we may be subject to, among other things, fines, suspension or withdrawal of regulatory approvals, product recalls, seizure of products, operating restrictions and criminal prosecution.

Privacy and data protection laws

We are also subject to laws and regulations in non-US countries covering data privacy and the protection of health-related and other personal information. For instance, EU member states and other jurisdictions have adopted data protection laws and regulations, which impose significant compliance obligations. Laws and regulations in these jurisdictions apply broadly to the collection, use, storage, disclosure, processing and security of personal information that identifies or may be used to identify an individual, such as names, contact information, and sensitive personal data such as health data. These laws and regulations are subject to frequent revisions and differing interpretations,

As of May 2018, the General Data Protection Regulation (GDPR) replaced the Data Protection Directive with respect to the processing of personal data in the European Union. The GDPR imposes many requirements for controllers and processors of personal data, including, for example, higher standards for obtaining consent from individuals to process their personal data, more robust disclosures to individuals and a strengthened individual data rights regime, shortened timelines for data breach notifications, limitations on retention and secondary use of information, increased requirements pertaining to health data and pseudonymised (i.e., key-coded) data and additional obligations when we contract third-party processors in connection with the processing of the personal data. The GDPR allows EU member states to make additional laws and regulations further limiting the processing of genetic, biometric or health data. Failure to comply with the requirements of GDPR and the applicable national data protection laws of the EU member states may result in fines of up to €20,000,000 or up to 4% of the total worldwide annual turnover of the preceding financial year, whichever is higher, and other administrative penalties.

Japan

Japanese drug regulation

Non-clinical studies and clinical trials

Being a member of the International Conference on Harmonization (ICH), Japan has pharmaceutical regulations fundamentally similar to those of the United States or EU.

Non-clinical studies are performed to demonstrate the health safety of new chemical or biological substances. Non-clinical studies must be conducted in compliance with the principles of Japanese good laboratory practice (GLP) which reflect the Organization for Economic Co-operation and Development requirements. Currently, Japan and EU have a mutual recognition agreement for GLP, and data generated compliant with EU requirements will be accepted by the Japanese authorities. There is no similar agreement with the United States.

Clinical trials of medicinal products in Japan must be conducted in accordance with Japanese regulations based on ICH guidelines governing good clinical practices (GCP). They focus on ethics of the clinical trial and protection of the privacy of the trial subjects. If the sponsor of the clinical trial is not established within Japan, it must appoint an entity within the country to act as its caretaker who should be authorized to act on the sponsor's behalf. The sponsor must take out a clinical trial insurance policy, and, according to the industry agreement, should put in place a common compensation policy for the injuries from the trial.

Prior to the commencement of human clinical studies, the sponsor must complete evaluation of the safety of the investigative product, and submit a clinical trial notification and the protocol to the authorities in advance, upon agreement of the IRB of the participating institutions. When the authorities do not comment on the notification, the sponsor may proceed with the clinical trial.

Any substantial changes to the trial protocol or other information submitted must be cleared by the IRB and notified to the authorities. Medicines used in clinical trials must be manufactured in accordance with good manufacturing practice (GMP).

Product approval

To market a medicinal product in Japan, we must obtain regulatory approval. To obtain regulatory approval of an investigational medicinal product, we must submit a new drug application. The process for doing this depends, among other things, on the nature of the medicinal product and there are currently a few different pathways for approval. If the product is designed for treating certain "difficult diseases" or those whose patient size is limited, we may be able to obtain designation as an orphan drug product if it demonstrates unique therapeutic value. Approval application for such designated orphan products will be processed on an expedited basis and the authorities' requirement for clinical data will be much limited. Separately, the latest amendment to the law introduced separate pathways for (i) truly innovative products with a unique mode of action and (ii) those which will satisfy unmet medical needs. These products will also be processed on an expedited basis.

The evaluation of applications will be based on an assessment of the risk-benefit balance of the product on the basis of scientific criteria concerning its quality, safety and efficacy. Once the review organization complete its review task, the matter will be considered by the advisory committee of experts, and the government will grant approval upon positive recommendation from the committee.

The volume and quality of the clinical data will be the key determinant of the approval decision. Clinical trial data generated overseas will be accepted as part of the data package consistent with the ICH recommendation. Typically, a limited dose response clinical trial for Japanese subjects is required to ensure that data are extrapolatable for the Japanese population. In a more recent development, the authorities encourage manufacturers to organize an international joint clinical trial with some Japanese participation under a joint protocol, to expedite the clinical trial process. Regulatory approval does not expire.

Licensing requirement

Separate from the approval requirement, it is also mandatory to possess a distribution license of an appropriate class for the manufacturer to commercially distribute the product in Japan. Non-Japanese companies who possess only the product approval may designate an appropriate license holder in Japan to commercially distribute the product, rather than distributing it on its own. The license is valid for 5 years.

Intellectual Property

Exclusive License Agreement with Children's Hospital Medical Center, d/b/a Cincinnati Children's Hospital Medical Center

On June 1, 2021 (the "Effective Date"), the Company entered into a license agreement with Children's Hospital Medical Center, d/b/a Cincinnati Children's Hospital Medical Center ("CHMC") to develop and commercialize certain CHMC patents and related technology directed at a virus-like particle (VLP) vaccine platform that utilizes nanoparticle delivery technology, which may have potential broad application to develop vaccines for multiple infectious diseases ("the CHMC Agreement"). The license is exclusive, worldwide, and is for all uses (other than the "Excluded Field" of immunization against, and prevention, control, or reduction in severity of gastroenteritis caused by Rotavirus and Norovirus in China and Hong Kong). The license is sublicensable with prior CHMC written approval consistent with the terms of the CHMC Agreement.

The CHMC Agreement includes the below patents, which we refer to as the "Licensed Patents", and any divisionals, continuations and continuations-in-part thereto (solely to the extent that the claims in the continuations-in-part are directed to the subject matter specifically claimed in the Licensed Patents, and they have the same priority date as the Licensed Patents, but do not include any different or additional claims), and any patents resulting therefrom:

U.S. Patent Application No.	U.S. Patent No.	Granted Claim Type	U.S. Expiration	Foreign Counterparts
12/797,396	8,486,421	Compositions of the vaccine/vaccine platform	1/13/2031	CN107043408B EP2440582B1 JP5894528B2
13/924,906	9,096,644	Method of treatment	9/20/2030	CN107043408B EP2440582B1 JP5894528B2
13/803,057	9,562,077	Compositions of the vaccine platform	4/10/2034	none
16/489,095	pending	pending**	[3/15/2038]*	Pending applications in Canada, China, EU and Japan
63/149,742 (filed 2/16/2021)	pending	pending**	[February 2042]#	TBD
63/162,369 (filed 3/17/2021)	pending	pending**	[March 2042]#	TBD

* Projected expiration if patent issues: 20 years from earliest non-provisional application filing date.

\# Non-provisional application not yet filed. Expiration projected 21 years from provisional application filing date. Dependent on timely conversion to non-provisional application and issuance of patent.

** This is a pending application. Claim type will be determined after U.S. prosecution is complete. The claim type sought includes compositions of the vaccine and vaccine platform.

The CHMC Agreement also grants the Company a non-exclusive limited license to use and copy internally any technical information in existence and known before the Effective Date by CHMC solely as necessary for the use and practice of the Licensed Patents (the “Technology”).

The term of the CHMC Agreement begins on the Effective Date and extends on a jurisdiction by jurisdiction and product by product basis until the later of: (i) the last to expire Licensed Patent; (ii) ten (10) years after the first commercial sale; or, (iii) entrance onto the market of a biosimilar or interchangeable product. CHMC has reserved the right to practice, have practiced, and transfer the Licensed Patents and Technology for research and development purposes, including education, research, teaching, publication and public service, but not to use or practice the Licensed Patents or Technology in Field of Use for any commercial or profit purpose.

The Licensed Patents granted to the Company under the CHMC Agreement are also subject to any rights of the United States federal, state and/or local Government(s), as well as nonprofit entities, if certain patents or technologies were created in the course of Government-funded or non-profit entity-funded research. The CHMC Agreement also contains compulsory licensing provisions under which CHMC must notify the Company in writing whenever CHMC may become aware of third parties that are interested in obtaining rights to the Licensed Patents or Technology for purposes that are beyond the scope of the Company’s development and commercialization plan. The Company may elect to pursue the new purposes itself (and negotiate commercially reasonable development targets), or enter into sublicense negotiations with the interested third party. However, if the Company fails to meet its development targets for the new purposes or fails to enter into a sublicense agreement with the interested third party within nine (9) months of the notice from CHMC, then the new purpose will be excluded from the license grant and CHMC will be free to pursue licensing of the Licensed Patents or Technology within the Excluded Field to an interested third party.

Any patented modification, alteration or improvement of any invention claimed in a Licensed Patents or Technology which is conceived or reduced to practice solely by the Company (“Company Improvement”) is owned by the Company; however, for any such Company Improvement, the Company will automatically grant to CHMC a worldwide, perpetual, sublicensable, nonexclusive, paid-up, royalty-free license to use any Company Improvements solely for clinical or non-clinical, non-commercial research, testing, educational and patient care purposes. The CHMC Agreement also provides the Company with an option to license any CHMC or jointly patented modification, alteration or improvement of any invention claimed in a Licensed Patent (“CHMC Improvement” and “Joint Improvement, respectively”), with option fee for each Improvement that the Company elects to include in the license grant of the CHMC Agreement.

The Company is required to pay CHMC an aggregate of up to $59.75 million upon the achievement of specified development milestones, of approximately $0.5 million, regulatory milestones, of approximately $1.25 million and commercial milestones, of approximately $58 million (excluding any royalty arrangements). In the event the Company enters into a sublicense agreement with a third party who is not an affiliate, then the Company is obligated to pay CHMC a percentage of all non-royalty sublicensing revenue. Specifically, the Company must pay twenty-five percent for revenue received from the sublicensee prior to first net sale of a licensed product, fifteen percent for revenue received after first net sale of a licensed product or five percent after the first sale of a second licensed product. No annual maintenance fee is required.

Pursuant to the CHMC Agreement, the Company paid to CHMC a one-time low ten-thousands initial license fee; thereafter, the Company is required to pay a low hundred-thousands deferred license fee upon the earlier of the Company’s first to occur convertible debt or equity raise after the Effective Date. On the one year anniversary of the Effective Date, the Company will be required to pay to CHMC an additional deferred low hundred-thousands license fee.

Under the CHMC Agreement, the Company is obligated to use commercially reasonable efforts to bring licensed products to market through diligent research and development, testing, manufacturing and commercialization and to use best efforts to make all necessary regulatory filings and obtain all necessary regulatory approvals, and achieve milestones relating to development and sales, and report to CHMC on progress. The Company will also be obligated to pay the agreed upon development milestone payments to CHMC.

Development milestones include: (i) IND filings of each Licensed Product; (ii) BLA or equivalent allowed for Licensed Product in U.S. or E.U.; (iii) first commercial sale of licensed product in the U.S.; (iv) first commercial sale of licensed product in the E.U.; (v) first commercial sale of licensed product in Japan; (vi) first commercial sale in Rest of World (ROW); (vii) conclusion of the first calendar year. Pursuant to the terms of the CHMC Agreement, if the Company fails to achieve milestones or make milestone payments on certain milestones, and cannot mutually agree with CHMC on an amendment to the milestones, then CHMC will have the option of converting any and all of such exclusive licenses to nonexclusive licenses.

In addition to the fees discussed above, beginning on the first Net Sale, the Company will pay CHMC running royalties on a quarterly basis as a percentage of Net Sales (as defined in the CHMC Agreement) of the Company, its affiliates and any subsidiaries. Similarly, in the event the Company enters into a sublicense agreement, the Company shall pay CHMC a percentage of all non-royalty sublicensing revenues received from the sublicensee. There are single digit royalty rates for products and processes for P-Particle VLP Bivalent vaccine for norovirus and rotavirus; for products and processes for Universal Flu Vaccine(s); and for all other products or processes for other indications. To date, no payments have been made related to the milestones or royalties. Before any Valid Claims (as defined in the CHMC Agreement) exist, the running royalty rates are reduced by fifty percent (50%).

The CHMC Agreement also contains an anti-stacking provision pursuant to which in the event the Company is legally required to pay royalties to one or more third parties whose patent rights dominate the Licensed Patents, and would therefore be infringed by exercise of the license rights granted in the CHMC Agreement, the Company may reduce running royalty payments by fifty percent (50%). In the event the Company grants sublicenses, the Company is obligated to pay CHMC as follows: (i) specified percentage of revenue received prior to first Net Sale of first Licensed Product; (ii) specified percentage for revenue received after first Net Sales of first Licensed Product but before first Net Sales of second Licensed Product; or, (iii) specified percentage for revenues received after first Net Sales of second Licensed Product.

CHMC reserved the first and sole right, using in-house or outside legal counsel selected by CHMC, to prepare, file, prosecute, maintain and extend patents and patent applications, and the Company agreed to reimburse CHMC for its legal and administrative costs incurred in the course of doing such. The Company also agreed to reimburse CHMC for incurred legal fees as of the Effective Date. CHMC will provide the Company a reasonable opportunity to comment during prosecution and will consider the Company's comments, but CHMC retained control over all final decisions. If CHMC elects to not be responsible for the prosecution or maintenance of any such patents, the Company will receive a sixty (60) days' written notice upon which the Company may elect, at the Company's expense, to assume the responsibilities and obligations to prosecute and maintain the patents (among other things); thereafter, the Company will use reasonable efforts to give CHMC an opportunity to comment, but the final decision with respect to such matter will remain with the Company.

The CHMC Agreement contains no CHMC representations or warranties. The CHMC Agreement also requires the Company to indemnify CHMC and other related parties against all claims, suit, actions, demands, judgments, or investigations arising out of any product the Company produces under the CHMC Agreement, as set forth in the CHMC Agreement, and requires the Company, beginning with the earlier of the first clinical trial or commercial sale or other commercialization to obtain liability insurance.

CHMC will have the first and sole right but not the obligation, at its own expense, to initiate an infringement suit or other appropriate actions against third party infringers and receives all therefrom. For joint suits initiated against third party infringers and receives damages or profits recovered therefrom. In the event CHMC does not, within six (6) months after becoming aware of infringement, secure cessation of the infringement, the Company will have the right to initiate suit at its own expense. Any damages or profits that the Company recovers will be treated as Net Sales subject to royalties after the Company has been compensated for its costs in handling such action. In the event of a joint infringement suit, the Company and CHMC will agree in writing who will control the action and how cost and recoveries will be shared.

The Company may terminate the CHMC Agreement for convenience, at any time prior to first commercial sale of a product or process by providing one hundred and eighty (180) days' written notice to CHMC. It may also terminate for a CHMC uncured material breach. CHMC may terminate the CHMC Agreement for an uncured Company material breach or insolvency or bankruptcy. In the event the Company's material breach is for failure to meet any of the milestone payments, the Company is entitled to a nonexclusive license to continue developing indications that have already entered development at any stage or in which the Company has invested in developing. CHMC may also terminate the CHMC Agreement to the fullest extent permitted by law in the countries of the worldwide territory, in the event the Company or its affiliates challenge or induce others set up challenges to the validity or enforceability of any of the Licensed Patents and the Company will be obligated reimburse CHMC for its costs, including reasonable attorneys' fees.

Option Agreement between Oxford University Innovation Limited and Blue Water Vaccines, Inc.

On December 18, 2018, the Company entered into an option agreement with Oxford University Innovation Limited ("OUI"), pursuant to which the Company paid an option fee of between $10,000 to $20,000, to OUI in exchange for a period of exclusivity, in advance of a fundraising of fifteen million dollars ($15,000,000). Under the option agreement, the Company has the right to exercise the option for the grant of the right to the Company to an exclusive, worldwide license to PCT Patent Application number PCT/GB/2017/052510, any patents granted in response to that application, any corresponding foreign patents and applications deriving priority from that application, and any addition, continuation, continuation-in-part, division, reissue, renewal or extension based thereon, and related know-how and confidential information (the "Technology").

Exercise of the option by the Company was conditional upon the Company submitting a business plan for the subsequent two years, including a development plan for the technology and a financial projection, demonstrating the Company's ability to develop the Technology and evidence of the Company's solvency and receipt of fifteen million dollars ($15,000,000) in funds for the development of the Technology. The Company has agreed that, as a condition precedent to the license becoming effective, it must provide funding for three years of salary for Dr. Craig Thompson in Oxford's Department of Zoology, a minimum of four hundred and twenty thousand pounds (£420,000). No additional funds are required to fulfill the three-year salary commitment, at this time, and none are anticipated prior to the completion of the three year term.

License Agreement Between Oxford University Innovation Limited and Blue Water Vaccines, Inc.

On July 16, 2019, the Company entered into an exclusive, worldwide agreement ("OUI Agreement") with Oxford University Innovation Limited ("OUI"), pursuant to which the Company obtained an exclusive worldwide license for all fields to PCT Patent Application number PCT/GB/2017/052510, entitled "Immunogenic Composition," any patents granted in response to that application, any corresponding foreign patents and applications deriving priority from that application, and any addition, continuation, continuation-in-part, division, reissue, renewal or extension based thereon, and a nonexclusive license to related know-how and confidential information, as set forth in the below chart (the "Licensed Technology"):

U.S. Patent Application No.	U.S. Patent No.	Granted Claim Type	U.S. Expiration	Foreign Counterparts
16/326,749	11,123,422	Compositions and method of treatment	8/25/2037	Pending applications in Australia, Canada, China, EU and Japan
17/458,712	pending	pending**	[8/25/2037]*	

* Projected expiration if patent issues: 20 years from earliest non-provisional application filing date.

** This is a pending application. Claim type will be determined after U.S. prosecution is complete. The claim type sought includes compositions of the compositions and method of treatment.

The OUI Agreement has a term concluding ten years following the last to expire of all licensed patents and patent applications as defined under the terms of the OUI Agreement. The license was conditional upon the Company entering into a separate agreement with Oxford University to provide funding for three years' salary for Dr. Craig Thompson in the University's Department of Zoology, which amounts to a minimum of four hundred and twenty thousand pounds (£420,000), which was paid by the Company in January 2020. No additional funds are required to fulfill the three-year salary commitment, at this time, and none are anticipated prior to the completion of the three year term.

Improvements to the Licensed Technology as defined in the OUI Agreement belong to OUI and are included in the Licensed Technology. All Company Improvements of belong to the Company. The Company granted to OUI, and OUI subsequently granted to Oxford University, a non-transferable, irrevocable, perpetual, royalty-free license to use and publish the Licensed Technology and the Company's Improvements upon the Licensed Technology for non-commercial use. If a Licensed Product is covered by the Medicines Access Policy of Oxford University to promote, the Company shall adhere to the requirements of the Medicines Access Policy.

The Company is required to pay OUI milestone payments of up to an aggregate of $51 million upon the achievement of specified development milestones, of approximately $2.25 million, regulatory milestones, of approximately $9.5 million and commercial milestones, of approximately $39.5 million (excluding any royalty arrangements). An annual maintenance fee in the low tens of thousands will be required beginning in 2023 through launch, increasing to the hundreds of thousands until expiration or revocation of the last valid claim covering a licensed product, in which case the annual maintenance fee will no longer be required.

The Company did not pay a signing fee to OUI and is obligated to pay a single digit royalty on all net sales of licensed products, as defined in the OUI Agreement, as well as royalties between 20-30% on any sums received by the Company from any sublicensee (including all up-front, milestone and other one-off payments received by the Company from any sub-licenses or other contracts granted by the Company with respect to the licensed technology). After the expiration or revocation of the last Valid Claim (as defined in the OUI Agreement) covering a Licensed Product, a “step down” royalty rate shall apply to such Licensed Technology. If the Company has to pay royalties to a third party to use a proprietary manufacturing process proprietary adjuvants in order to make or have made a Licensed Product, the Company will be able to deduct from all royalty payments, up to a maximum amount of twenty-five percent (25%) of the royalties due to OUI. The OUI Agreement entitles the Company to supply a commercially reasonable quantity (not exceeding 5% of units sold in any quarter) of licensed products for promotional sampling.

In the event that royalties paid to OUI do not amount to the “minimum sum” under the OUI Agreement for a particular year, the Company is obligated to make up the difference between the royalties actually paid and such minimum sum. The minimum sums vary over time, and reduces to $0 once the “step down” applies. The minimum sums and milestone fees are indexed to the RPI (Retail Prices index for all items which is published in the United Kingdom by the Office for National Statistics, or any replacement of it) and will be increased or decreased as appropriate as set forth in the OUI Agreement.

The Company is obligated to use its best efforts to develop and market Licensed Products in accordance with its development plan report to OUI on progress and achieve the following milestones and must pay OUI nonrefundable milestone fees as follows when it achieves them: initiation of first Phase I study; initiation of first Phase II study; initiation of first Phase III/pivotal registration studies; first submission of application for regulatory approval (BLA/NDA); marketing authorization in the United States; marketing authorization in any EU country; marketing authorization in Japan; first marketing authorization in any other country; first commercial sale in Japan; first commercial sale in any ROW country; first year that annual sales equal or exceed certain thresholds.

The Company is obligated to pay, and has paid, a low 5-digit number of British pounds to OUI for any past patent expenses that were incurred prior to the execution of the OUI Agreement. Upon consultation with the Company and at the Company’s expense, OUI shall prosecute, use all reasonable endeavors to maintain and renew the patents throughout the duration of the OUI Agreement. The Company and OUI agreed to inform each other in writing of any misappropriation or infringement of any rights to the licensed technology; however, the Company has the first right to take legal action at its own cost in relation to any such misappropriation or infringement, but must discuss any proposed legal action with OUI and take into account any legitimate interest of OUI in the legal action that it takes. If the Company notifies OUI that it does not intend to take legal action in such matters, OUI may take any legal action at its own cost. All profits or damages recovered after unrecovered costs and expenses are deducted are treated as net sales for which royalties would be due.

OUI makes no warranties at all with regard to the Licensed Technology or whether use of it will infringe third party rights. The Company is required to indemnify OUI and Oxford University from all third party claims, damages, and liabilities asserted by third parties arising directly or indirectly from use of the Licensed Technology; marketing of Licensed Products; or breach of the OUI Agreement. The OUI Agreement is governed by English law and the parties agreed to submit to the exclusive jurisdiction of English Courts for resolution of any disputes arising out of or in connection with the OUI Agreement, with the exception of actions relating to intellectual property disputes or confidential information which may be brought in any court of competent jurisdiction.

Either party may terminate the OUI Agreement for an uncured material breach. The Company may terminate the OUI Agreement for any reason at any time upon six months’ written notice expiring after the third anniversary of the OUI Agreement. OUI may terminate immediately if the Company has a petition presented for its winding-up or passes a resolution for winding up other than for a bona fide amalgamation or reconstruction or compounds with its creditors or has a receiver or administrator appointed. OUI may also terminate if the Company opposes or challenges the validity of any of the patents or applications in the Licensed Technology; raises the claim that the know-how of

the Licensed Technology is not necessary to develop and market Licensed Products; or in OUI's reasonable opinion, is taking inadequate or insufficient steps develop or market Licensed Products and does not take any further steps that OUI requests by written notice within a reasonable time.

Exclusive License Agreement between St. Jude Children's Research Hospital, Inc. & Blue Water Vaccines

On January 27, 2020 (the "Effective Date"), the Company entered into an exclusive, worldwide license agreement with St. Jude Children's Research Hospital, Inc. ("St. Jude"), pursuant to which St. Jude granted the Company an exclusive license to develop licensed products and produce vaccines for use in humans ("St. Jude Agreement") under U.S. Provisional Patent Application No. 61/537,290 (U.S. Patent No. 9,265,819 issued on February 23, 2016), and U.S. Provisional Patent Application No. 62/817,748 (filed March 13, 2019), and any issued patents, divisions, continuations, continuations-in-part, to the extent that the claims are directed to subject matter described in the above-referenced patent applications and are entitled to the priority date of the existing patent rights, re-examinations, substitutions, renewals, restorations, additions, or registrations thereof, as well as non-United States counterparts thereof, and extensions and supplementary protection certificates thereon ("Patent Rights"), all as set forth in the below chart:

U.S. Patent Application No.	U.S. Patent No.	Granted Claim Type	U.S. Expiration	Foreign Counterparts
14/345,988	9,265,819	Compositions and method of treatment	9/19/2032	none
17/602,414#	pending	pending**	[3/12/2040]*	Pending Applications in: Australia, Brazil, Canada, China, Europe, Hong Kong, Japan and Korea

* Projected expiration if patent issues: 20 years from earliest non-provisional application filing date.
\# U.S. National stage entry of WO 2020/183420 (PCT/IB2020/052250).
** This is a pending application. Claim type will be determined after U.S. prosecution is complete. The claim type sought includes compositions and method of treatment.

The license is sublicensable consistent with the terms and conditions of the St. Jude Agreement, provided that the Company remains responsible for the performance by each of its sublicensees. The license is subject to any government rights the United States has reserved, and St. Jude retained the right to make, have made, provide and use for St. Jude's non-commercial research and clinical purposes, including the right to distribute St. Jude's biological material disclosed and claimed in the Patent Rights for non-profit academic research use to non-commercial entities as is customary in the scientific community and to sell the biological materials as research reagents for research use only by the scientific community.

The Company is required to pay St. Jude milestone payments of up to an aggregate of $1 million upon the achievement of specified development milestones, of approximately $0.2 million, regulatory milestones, of approximately $0.3 million and commercial milestones, of approximately $0.5 million (excluding any royalty arrangements). In the event the Company enters into a sublicense agreement with a third party who is not an affiliate, then the Company is obligated to pay St. Jude fifteen percent of any sublicense consideration, subject to specified exclusions, but including any upfront or milestone fees and including any premium paid by sublicensee over Fair Market Value (as defined in the agreement) for the Company's stock.

In exchange for the licenses, the Company paid St. Jude an initial license fee between $10,000 to $20,000 and is required to pay an annual maintenance fee between $10,000 to $20,000 beginning on the first anniversary of the Effective Date (which is waived if all of the developmental milestones scheduled for completion before such annual fee is due have been achieved), milestone payments, patent reimbursement, and running royalties based on net sales of licensed products under the St. Jude Agreement.

Under the St. Jude Agreement, the Company is obligated to use commercially reasonable efforts to develop and commercialize the licensed product(s). If the Company fails to achieve the development milestones contained in the St. Jude Agreement, and if the Company and St. Jude fail to agree upon a mutually satisfactory revised time line, St. Jude will have the right to terminate the St. Jude Agreement.

The milestones include the following events: (i) complete IND enabling study by 2020; (ii) Initiate animal toxicology study by last half of 2020; (iii) file IND by first half of 2021; (iv) complete Phase I Clinical Trial by first half of 2022; (v) commence Phase II Clinical Trial by first half of 2024; (vi) commence Phase III Clinical Trial by 2026; and, (vii) regulatory approval, U.S. or foreign equivalent by 2026. Upon achievement of certain development and commercialization milestones, the Company is required to make milestone payments to St. Jude between the achievement of certain milestones (commencement of a Phase III clinical trial through first commercial sale).

Additionally, the Company is obligated to make running single-digit royalty payments payable, for each licensed product(s) sold by the Company, its affiliates or sublicensees, based on the net sales for the duration of the St. Jude Agreement. Furthermore, the Company is obligated to pay a percentage between 10-20% of other consideration received for any sublicenses.

The Company reimbursed St. Jude a 5-digit sum for certain patent costs incurred by St. Jude prior to the Effective Date of the St. Jude Agreement, and is obligated to reimburse St. Jude for reasonable patent costs incurred by St. Jude subsequent to the Effective Date.

The Company is responsible for and shall bear all expenses relating to the filing, prosecution, and maintenance of all patent rights licensed under the St. Jude Agreement. The Company has the first right to enforce any patent against infringement, and shall keep St. Jude informed of the status of such; however, before the Company may commence any action with respect to any such alleged infringement, the Company shall take into consideration the views of St. Jude and the potential effect on the public interest.

Prior to initial human testing or first commercial sale of a licensed product, and thereafter so long as the licensed products are being sold in any particular country, the Company (and its sublicenses) is required to obtain and maintain insurance to cover its indemnity obligations, and to obtain and maintain product liability insurance coverage.

St. Jude represented and warranted that it has good and marketable title to the Patent Rights, but made no other representations and warranties. The term of the agreement commenced on the Effective Date, and shall continue, in each country, until the date of expiration of the last to expire valid claim included within the Patent Rights in that country. Either party may terminate the St. Jude Agreement in the event the other party (a) files or has filed against it a petition under the Bankruptcy Act (among other things) or (b) fails to perform or otherwise breaches its obligations under the St. Jude Agreement, and has not cured such failure or breach within sixty (60) days. The Company may terminate for any reason on thirty (30) days written notice.

Manufacturing and Supply

We currently do not own or operate any manufacturing facilities, but our strategic partnership with Ology Bioservice (which was later acquired by National Resilience, Inc.) (“Ology”) provides us with access to substantial resources to facilitate an independent supply path to the market. Ology is a leading global contract manufacturer with deep domain expertise and experience in large and small-scale production of clinical, as well as commercial-stage products. We have entered into agreements with Ology to secure capacity, technical expertise and resources to support the production of our products and processes that are intended to scale to commercial scale at Ology or other commercial manufacturing sites.

In July 2019, we entered into a development and manufacturing master services agreement with Ology, which we refer to, as amended, as the Ology Agreement, pursuant to which Ology is obligated to perform manufacturing process development and clinical manufacture and supply of components.

Under the Ology Agreement, we will pay Ology agreed upon fees for Ology’s performance of manufacturing services, and we will reimburse Ology for its out-of-pocket costs associated with purchasing raw materials, plus a customary handling fee. The Company entered into an initial Project Addendum on October 18, 2019 and the Company was required to pay Ology an aggregate of approximately $4 million. Due to unforeseen delays associated with COVID-19, the Company and Resilience entered into a letter agreement dated January 9, 2020 to stop work on the project. The Company paid Ology $100,000 for services, of which $48,600 remains as prepaid expense as of December 31, 2020 and June 30, 2021. The second Project Addendum was executed May 21, 2021 and the Company is obligated to pay Ology an aggregate amount of approximately $2.8 million, plus reimbursement for materials and outsourced testing, which will be billed at cost plus 15%.

Either party may terminate a Project Addendum and/or the Ology Agreement upon the material breach of any provision of this Agreement by the other Party if such breach is not cured by the breaching party within thirty (30) calendar days after receipt by the breaching Party of written notice of such default. The Company may terminate the Ology Agreement or the associated Project Addendum for any or no reason upon sixty (60) days' prior written notice to Ology.

For additional details regarding our relationship with Ology, see Note 5 to our financial statements included elsewhere in this prospectus.

Employees

As of September 30, 2021, we had 2 full-time and 7 subcontracted employees. None of our employees are represented by a collective bargaining agreement, and we have never experienced any work stoppage. We believe we have good relations with our employees.

Properties and Facilities

We are currently leasing an office located at 201 E Fifth Street, Suite 1900, Cincinnati, OH 45202, which is renewed on a monthly basis. All of our research and development is performed on the premises of our third-party providers.

Legal Proceedings

From time to time we may be involved in various disputes and litigation matters that arise in the ordinary course of business. We are currently not a party to any material legal proceedings.

Changes in and Disagreements with Accountants

None.

Corporation Information

We were incorporated in Delaware on October 26, 2018. Our principal executive offices are located at 201 E Fifth Street, Suite 1900, Cincinnati, OH 45202, and our telephone number is (513) 620-4101. Our corporate website address is *www.bluewatervaccines.com*. The information contained on or accessible through our website is not a part of this prospectus, and the inclusion of our website address in this prospectus is an inactive textual reference only.

MANAGEMENT

Executive Officers and Directors

The following table provides information regarding our executive officers and directors as of September 30, 2021:

Name	Age	Position(s)
Executive Officers and Directors		
Joseph Hernandez	49	Chief Executive Officer and Director
Jon Garfield	56	Interim Chief Financial Officer[(1)]
Erin Henderson	47	Chief Business Officer
Non-Employee Directors		
Kimberly Murphy	58	Director
John Rice, Ph.D.	71	Director[(2)]
Allan L. Shaw	57	Director
Michael Venerable	58	Director
James Sapirstein	60	Director Nominee

(1) Mr. Garfield, who currently serves as our interim chief financial officer, will become our chief financial officer upon the consummation of this offering.

(2) Mr. Rice will be resigning from his position as a director effective upon the consummation of this offering.

Executive Officers and Directors

Executive Officers

Joseph Hernandez

Joseph Hernandez has been the Chief Executive Officer & Executive Chairman for Blue Water Vaccines, Inc. since October 2018. He has a background in company creation, early stage technology development, as well as private and public market financing. He brings leadership to the team, backed by a strong educational foundation in biology, medicine, molecular genetics, microbiology, epidemiology, marketing, and finance. Over the course of his career, he has founded or led eight entrepreneurial companies in cutting edge areas of healthcare and pharmaceuticals. After years of building his career at Merck & Co. (NYSE:MRK) from December 1998 to January 2001 and Digene from 2005 to 2009 (acquired by Qiagen (NYSE:QGEN)) from 2005 to 2009, Mr. Hernandez founded and became the President and CEO of Innovative Biosensors from 2004 to 2009. Later, Mr. Hernandez served as the Founder and Chairman of Microlin Bio Inc. from August 2013 to January 2017 and as Chairman of the Board of Ember Therapeutics (OTCMKTS:EMBT) from April 2014 to January 2019. He was also the Chairman of Sydys Corporation from May 2016 to January 2019. In 2018, Mr. Hernandez founded Blue Water Vaccines, an early stage biotechnology company focused on manufacturing a universal influenza vaccine in partnership with the University of Oxford in England. He has served as Chairman of Blue Water Vaccines, Inc. since 2019. Most recently, in January 2020, he founded and in May 2020 sold Noachis Terra, Inc. (acquired by Oragenics (NYSE:OGEN)) a company developing a vaccine for COVID-19. From May, 2020 to September 2021, Mr. Hernandez was also the chairman and chief executive officer of Blue Water Acquisition Corp. (“BWAC”), a special purpose acquisition company which completed its initial public offering in December 2020. On September 9, 2021, Blue Water Acquisition Corp. consummated a business combination with Clarus Therapeutics Holdings Inc. (Nasdaq:CRXT) (“Clarus”). Mr. Hernandez currently serves as a director of the post-combination entity, Clarus, where he serves as a member of the Audit and Compensation Committees. He completed his undergraduate studies in Neuroscience, M.Sc. in Molecular Genetics and Microbiology, M.B.A. all at the University of Florida and is completing his M.Sc. in Chronic Disease Epidemiology and Biostatistics at Yale University.

Jon Garfield

Jon Garfield has been our interim Chief Financial Officer since September 2021 and will be our Chief Financial Officer upon the consummation of this offering. Mr. Garfield has over 20 years of financial leadership experience, including with healthcare companies. Mr. Garfield regularly provides consulting services to private equity funds and privately held companies. Mr. Garfield has served as the CEO of Unity MSK since February 2021. He has served as a

consultant of Bay State Physical Therapy from June 2018 to February 2019 and also as a director beginning in February 2019. From 2016 to 2017, Mr. Garfield was the CFO of Pyramid Healthcare, also a private equity based healthcare company. Prior to Pyramid Healthcare, Mr. Garfield joined Monte Nido as CFO in 2012 until 2016. Before Monte Nido, he served as CFO of Clearant, Inc., a publicly-traded medical device company, and Network IP and Simplified Development, where he oversaw the finance and treasury functions, implemented systems upgrades, and pursued a number of growth initiatives. Mr. Garfield was previously a Co-Founder and Vice President of Acquisitions for Coach USA, a consolidator of ground transportation entities throughout North America, and was heavily involved in over 50 acquisitions and the eventual IPO of the company. Earlier in his career, he held positions with PricewaterhouseCoopers and Arthur Andersen. Mr. Garfield was the Chief Financial Officer of BWAC from December 2020 until it completed a business combination with Clarus in September 2021.Mr. Garfield received a B.B.A. in accounting from the University of Texas.

Erin Henderson

Erin Henderson has been the Chief Business Officer for Blue Water Vaccines, Inc. since September 2020 and has extensive experience in program and project management, business operational management, marketing, fundraising and public-private partnership development and implementation. She joined the company in September 2019. Prior to joining Blue Water Vaccines, since 2010, Ms. Henderson was the Founder and Managing Partner for The Aetos Group, a management consulting company working with public, private, governmental and non-governmental organizations focused on operational efficiency, Lean Six Sigma implementation, revenue development strategy and real estate acquisition strategy. Erin began her career at Lockwood Greene Engineers, followed by The Facility Group. She led local, state and federal governmental relations for the University of West Georgia and was responsible for identifying and securing financial support from both the public and private sector. Erin completed her undergraduate studies in Chemical Engineering from Auburn University. Erin serves on the Board of the Greater Gainesville Chamber of Commerce and the Board of Danscompany of Gainesville.

Significant Employees

Dr. Ronald R. Cobb, Ph.D.

Ron Cobb, Head of Science and Discovery for Blue Water Vaccines, Inc. since August 2021, is a Geneticist and Molecular Biologist with 25 years of pharmaceutical R&D and manufacturing experience. Dr. Cobb began his career at Research Triangle Institute in 1985 where he had the unique opportunity to work with Drs. Wall and Wani, who discovered Camptothecin and Taxol. At Tanabe Research Laboratories, Dr. Cobb initiated discovery programs seeking small molecule inhibitors of inflammatory diseases both while supporting all internal drug discovery screening efforts with protein expression services. In 1999 Dr. Cobb was recruited to Berlex Biosciences (US Division of Schering AG) to head up the protein expression section of the Protein Expression and Gene Therapy Group, where he supported gene expression for both research and clinical development phase project and was a member of the Scientific Advisory Committee and Worldwide Antibody Development Committee for Schering. At the end of 2005, Dr. Cobb joined the Research and Development Group at RTI Biologics where he was named the Director of Research, then to the Director of Research and Development. Under his guidance, 21 new products were released in 2009. Dr. Cobb joined Nanotherapeutics, Inc. (now National Resilience) as Vice President of Biologics in January 2011 and was Chief Scientific Officer in 2014 through 2021 and was PI for over $200M in drug development contracts. He has co-authored over 60 peer-reviewed manuscripts and is currently working with BioDeals, LLC as Managing Director. Dr. Cobb received a BA in Biology at Wake Forest University and a Ph.D. in Biochemistry from the Medical College of Georgia.

Andrew Skibo, Ph.D.

Mr. Skibo has been the Head of Biologics Operations for Blue Water Vaccines, Inc. since June 2021. Mr. Skibo is a seasoned biopharmaceutical operations executive with deep cross-functional experience in international biopharmaceutical manufacturing, process scale-up, internal and external supply chain network design strategy and major capital project expansions. He has extensive international experience having been responsible for the design and startup of major pharmaceutical manufacturing facilities in USA, UK, Europe, Russia, Singapore and China. He is deeply familiar with all aspects of biotechnology product scale up and launch, having held related roles since the founding days of large-scale biotechnology commercial production. He has a broad understanding of many enterprise operations having held roles in Research and Process Development, Commercial/Business Development, Engineering and Strategic Planning.

Mr. Skibo served as EVP Operations at Medimmune, and Head of Biologics Operations at Astra Zeneca for eleven years. He retired from that full time role in April 2019, but continues to serve as Technical Advisor to EVP Operations, AstraZeneca. In his role, he was responsible for the development and improvement of AstraZeneca's mono-clonal antibody operations and influenza seasonal and pandemic LAIV Flu operations. He developed the network strategy for these operations and implemented them in ten plants across eight sites (including two new sites) in the USA, UK, Europe and China. He transformed a previously challenging regulatory quality environment (warning letter) to best in class status. He oversaw the development of four BLA's and biologics product launches in 2017 to 2019, and has held related roles for nine product launches in his career.

In both his role with MedImmune/AstraZeneca and his role on the Board of ISPE, Mr. Skibo routinely interfaced with leadership levels of major international regulatory agencies, especially the FDA. He was instrumental in resolving a dead-locked product approval/cGMP regulatory issue, involving multiple firms, with the FDA associated with the recent launch of one of AstraZeneca's most significant oncology products.

Mr. Skibo received his B.S. degree in Chemistry and his M.S degree in Chemical Engineering from MIT. He holds patents in polymer film extrusion from his original career at Monsanto. He has served as a member of the Mayor's Fiscal Advisory Committee in San Francisco and has been a member and chairman of the Board of Supervisors in Birmingham/Chester County, PA.

Brian Price, Ph.D.

Brian Price has been Blue Water Vaccine, Inc.'s Head of Technology Strategy since September 2020 after being the Chief Compliance Officer from August 2019 to September 2020. Mr. Price is an experienced professional in FDA-regulated industries with a focus in CMC Development, regulatory compliance and QC analytical method development and validation. He has a successful track record of Business Development Growth with Government and Commercial funded toxicology, therapeutic and vaccine development, and analytical clientele. Brian's expertise is with molecular biology, microbiology, infectious disease, immunology, vaccines and drug discovery and development, and FDA compliance. His prior experience includes, from August 2018 to March 2019, as Vice-President of Pharmaceutical Development at Myonexus Therapeutics, Inc. and multiple positions with Battelle from November 2011 to August 2018, including his most recent role as Vice President of Business Development for the Health Business Unit. At Battelle, Brian supported sales for, directed and oversaw basic and applied research projects for a number of commercial and government clients in the areas of toxicology, vaccine and therapeutic efficacy evaluation, medical device development, environmental microbiology, assay development and validation, and vaccine production, including participating in the development of pre-clinical trial material for the next generation Anthrax vaccine based on recombinant Protective Antigen for VaxGen, Inc. Mr. Price completed is undergraduate studies in Microbiology and Ph.D. in Microbiology at The Ohio State University.

Non-Executive Directors

Allan L. Shaw, one of our directors since January 2020, brings more than two decades of public company financial, operational, and strategic global business leadership. Mr. Shaw is a highly regarded biopharma executive and board member with extensive senior global strategic, financial, M&A, operational, capital markets and governance experience. Mr. Shaw's notable accomplishments include raising more than $4 billion in public/private financings (including 2 IPOs), scaling a company from $20 million to $750 million in revenue as well as being involved with the sourcing/development/commercialization of various drug products in numerous therapeutic areas. Mr. Shaw has been the chief financial officer of Portage Biotech Inc. (PBT.U: CSE, PTGEF: OTC Markets) since May 2020. Mr. Shaw is the founder and since 2005, has served as senior managing director, of Shaw Strategic Capital LLC, an international financial advisory firm focused on providing strategic financial counsel on a wide variety of issues such as general corporate finance, mergers and acquisitions, capital structuring, licensing and capital markets, and serving as financial consultant to private and public companies. Mr. Shaw was the Chief Financial Officer and Treasurer of Syndax Pharmaceuticals, Inc. from January 2016 to February 2017 and from December 2011 to September 2015, was Managing Director of Alvarez & Marsal LLC, a global professional services firm, where he led their biopharmaceutical consulting practice. Mr. Shaw has served on five public boards including chairing two audit committees, two compensation committees, and is currently involved with a portfolio of healthcare-related business endeavors. Mr. Shaw served as the Chief Financial Officer of Serono S.A. from November 2002 to May 2004; NewLead Holdings Ltd from October 2009 to July 2011; and Viatel, Inc. from November 1994 to June 2002. He currently serves on the board of directors of Edith & Carl Marks

JCH of Bensonhurst, a non-profit organization, and chairs their finance committee. Mr. Shaw is a certified public accountant in the State of New York as well as a Chartered Global Management Accountant (CGMA). Mr. Shaw received a B.S. from the State University of New York at Oswego College.

Kimberly Murphy, one of our directors since January 2020, has more than 25 years of experience at leading pharmaceutical companies including Novartis (NYSE: NVS) and Merck & Co (NYSE: MRK). In her distinguished career at Merck, she rose through various public affairs and business roles to leadership positions as Region Marketer for U.S. Commercial Operations, U.S. Marketing Leader for Adult Vaccines and Director of the HPV/Gardasil Franchise. Most recently, Ms. Murphy served as currently the Vice President of Global Vaccines Commercialization Leader, Influenza Franchise, at GlaxoSmithKline (NYSE: GSK). Ms. Murphy has been with GSK since 2011, initially serving as VP of US Vaccines Customer Strategy from October 2012 to June 2014, then VP of the North America Vaccines Integration Planning from June 2014 to May 2015, followed by VP and Global Marketing Head for the Shingles Vaccines from May 2015 to February 2016, before transitioning to the Global Vaccines Commercialization Leader for the Influenza Franchise. Kim has Board and Advisory experience that includes serving on the boards of Oragenics, Inc. (NYSE: OGEN) as well as the GSK Representative to the Biotechnology Industry Organization's Biodefense Advisory Council, and on the St. Joseph's University Pharmaceutical & Healthcare Marketing MBA Program's Advisory Board. Additionally, Ms. Murphy was a director of BWAC from December 2020 to September 2021, and since BWAC's business combination with Clarus Therapeutics Holdings Inc. (Nasdaq:CRXT), has continued to serve as chair of the post-combination entity's board of directors, and also she serves as a member of the Compensation and Nominating and Corporate Governance Committees. Ms. Murphy received a B.A. in English from Old Dominion University, a M.B.A. in Marketing from St. Joseph's University, and the Marketing Excellence Program from the Wharton School of University of Pennsylvania. She is well qualified to serve on our Board due to her extensive experience in the healthcare industry.

Mike Venerable has been one of Blue Water Vaccines, Inc.'s directors since April 2020. As CEO and managing director of CincyTech, Mike Venerable leads with experience from both sides of the table: as a software industry entrepreneur and executive, and a seasoned investment and venture capital professional. Mike joined CincyTech in 2006, helping to raise its inaugural fund. He served as managing director for a decade, evaluating investment opportunities, advising startup companies, and helping to build a network of investors and strategic partners and raise CincyTech Funds II- IV. Previously, Mike was co-founder and CEO of Talus, a leading data warehouse consultancy, which was acquired by Sagent Technology. Mike led the company's services organization through the company's successful IPO in 1999. He has specific experience in raising angel and venture capital, software business design and operation, software product management, business valuation, financial analysis and intellectual property. As an industry practitioner, Mike is an expert on data warehouse design, business intelligence and analytic applications and software development processes. He has consulted on strategic product development initiatives for leading technology companies, including Siebel, Advent and Micros. Mike served in the US Army as a Korean linguist after graduating from the University of Dayton.

James Sapirstein, who will serve as one of our directors upon the completion of this offering, has over 35 years of experience leading, founding, growing, and selling healthcare companies, specifically in the pharmaceutical space. Mr. Sapirstein is currently the President and CEO of AzurRx BioPharma (Nasdaq: AZRX), where he has been since October 2019. His career began in sales at Eli Lilly, eventually rising to Director of International Marketing at Bristol Myers Squibb from July 1996 to June 2000, and later led the launch of Viread (tenofovir) at Gilead Sciences, Inc. (Nasdaq: GILD), where he served as Global Marketing Lead from June 2020 to June 2002. From November 2006 to January 2011, he served as founding CEO of Tobira Therapeutics (Nasdaq: TBRA), then a private company, and later acquired by Allergan (NYSE: AGN). Since then, he has served as CEO of Alliqua Biomedical (Nasdaq: ALQA) from September 2012 to February 2014 and CEO of Contravir Pharmaceuticals (Nasdaq: CTRV from March 2014 to October 2018. He has been part of almost two dozen drug product launches and specifically either led or has been a key member of several HIV product launches into different new classes of therapeutics at the time. Additionally, Mr. Sapirstein holds board positions on Marizyme (OTCMKTS:MRZM) (Executive Chairman) since December 2018 Enochian Biosciences (Nasdaq: ENOB) since April 2018 and Leading Biosciences since March 2016. He previously served as a director of BioNJ from February 2017 to February 2019, an association of biopharma industries in New Jersey, from February 2017 to February 2019, RespireRX (OTCBB:RSPI) from April 2014 to January 2020, NanoViricides Inc. (NYSE: NNVC) from November 2018 to January 2020 and BWAC from December 2020 until its business combination with Clarus in September 2021. He is also a Board Director for BIO, the leading Biopharma Industries Organization promoting public policy and networking in the healthcare space, where he sits on both the Health Section and Emerging Companies Section Governing Boards. Mr. Sapirstein received a B.S. in Pharmacy from Rutgers University and his MBA from Fairleigh Dickinson University. He is well qualified to serve on our Board due to his extensive network from decades in the healthcare industry.

Family Relationships

There are no family relationships between or among any of the current directors, executive officers or persons nominated or charged to become directors or executive officers. There are no family relationships among our officers and directors and those of our subsidiaries and affiliated companies.

Board Composition

Our business and affairs are organized under the direction of our board of directors, which will continue to consist of five members following the consummation of this offering. Our board of directors will initially be divided into three classes, Class I, Class II and Class III, with members of each class serving staggered three-year terms. Our directors will be divided among the three classes as follows:

- the Class I directors will be Allan Shaw and Mike Venerable, and their terms will expire at our annual meeting of stockholders to be held in 2022;
- the Class II director will be James Sapirstein, and his terms will expire at our annual meeting of stockholders to be held in 2023; and
- the Class III directors will be Joseph Hernandez and Kimberly Murphy, and their terms will expire at our annual meeting of stockholders to be held in 2024.

Our Amended and Restated Certificate of Incorporation will provide that the authorized number of directors may be changed only by resolution of the board of directors. Our directors hold office until the earlier of their death, resignation, removal or disqualification, or until their successors have been elected and qualified. Our board of directors does not have a formal policy on whether the roles of Chief Executive Officer and Chairman of our board of directors should be separate. The primary responsibilities of our board of directors are to provide oversight, strategic guidance, counseling and direction to our management. Our board of directors meets on a regular basis. Upon completion of this offering, our Amended and Restated Bylaws will provide that the authorized number of directors may be changed only by resolution of the board of directors.

We have no formal policy regarding board diversity. Our priority in selection of board members is identification of members who will further the interests of our stockholders through his or her established record of professional accomplishment, the ability to contribute positively to the collaborative culture among board members, knowledge of our business and understanding of the competitive landscape.

Director Independence

The Nasdaq Marketplace Rules require a majority of a listed company's board of directors to be comprised of independent directors within one year of listing. In addition, the Nasdaq Marketplace Rules require that, subject to specified exceptions, each member of a listed company's audit, compensation and nominating and corporate governance committees be independent and that audit committee members also satisfy independence criteria set forth in Rule 10A-3 under the Exchange Act.

Under Rule 5605(a)(2) of the Nasdaq Marketplace Rules, a director will only qualify as an "independent director" if, in the opinion of our board of directors, that person does not have a relationship that would interfere with the exercise of independent judgment in carrying out the responsibilities of a director. In order to be considered independent for purposes of Rule 10A-3 of the Exchange Act, a member of an audit committee of a listed company may not, other than in his or her capacity as a member of the audit committee, the board of directors, or any other board committee, accept, directly or indirectly, any consulting, advisory, or other compensatory fee from the listed company or any of its subsidiaries or otherwise be an affiliated person of the listed company or any of its subsidiaries.

Our board of directors has reviewed the composition of our board of directors and its committees and the independence of each director. Based upon information requested from and provided by each director concerning his background, employment and affiliations, including family relationships, our board of directors has determined that each of Messrs. Allan Shaw and James Sapirstein as well as Ms. Kimberly Murphy, is an "independent director" as defined under Rule 5605(a)(2) of the Nasdaq Marketplace Rules. Our board of directors also determined that Messrs. Allan Shaw and James Sapirstein as well as Ms. Kimberly Murphy, who will comprise our audit committee following this offering, who will comprise our compensation committee following this offering, and Messrs. Allan

Shaw and James Sapirstein as well as Ms. Kimberly Murphy, who will be members of our nominating and corporate governance committee following this offering, satisfy the independence standards for such committees established by the SEC and the Nasdaq Marketplace Rules, as applicable. In making such determinations, our board of directors considered the relationships that each such non-employee director has with our company and all other facts and circumstances our board of directors deemed relevant in determining independence, including the beneficial ownership of our capital stock by each non-employee director.

Board Committees

Our board of directors has established three standing committees — audit, compensation and nominating and corporate governance — each of which operates under a charter that has been approved by our board of directors. Prior to the completion of this offering, copies of each committee's charter will be posted on the Investor Relations section of our website, which is located at *www.bluewatervaccines.com*. Each committee has the composition and responsibilities described below. Our board of directors may from time to time establish other committees.

Audit Committee

Our audit committee consists of Allan Shaw, who is the chair of the committee, Kimberly Murphy and James Sapirstein. Our board of directors has determined that each of the members of our audit committee satisfies the Nasdaq Marketplace Rules and SEC independence requirements. The functions of this committee include, among other things:

- evaluating the performance, independence and qualifications of our independent auditors and determining whether to retain our existing independent auditors or engage new independent auditors;
- reviewing and approving the engagement of our independent auditors to perform audit services and any permissible non-audit services;
- reviewing our annual and quarterly financial statements and reports, including the disclosures contained under the caption "Management's Discussion and Analysis of Financial Condition and Results of Operations," and discussing the statements and reports with our independent auditors and management;
- reviewing with our independent auditors and management significant issues that arise regarding accounting principles and financial statement presentation and matters concerning the scope, adequacy and effectiveness of our financial controls;
- reviewing our major financial risk exposures, including the guidelines and policies to govern the process by which risk assessment and risk management is implemented; and
- reviewing and evaluating on an annual basis the performance of the audit committee, including compliance of the audit committee with its charter.

Our board of directors has determined that Allan Shaw qualifies as an "audit committee financial expert" within the meaning of applicable SEC regulations and meets the financial sophistication requirements of the Nasdaq Marketplace Rules. In making this determination, our board has considered Mr. Shaw's extensive financial experience and business background. Both our independent registered public accounting firm and management periodically meet privately with our audit committee.

Compensation Committee

Our compensation committee consists of James Sapirstein, who is the chair of the committee, Kimberly Murphy and Allan Shaw. Our board of directors has determined that each of the members of our compensation committee is an outside director, as defined pursuant to Section 162(m) of the Internal Revenue Code of 1986, as amended, or the Code, and satisfies the Nasdaq Marketplace Rules independence requirements. The functions of this committee include, among other things:

- reviewing, modifying and approving (or if it deems appropriate, making recommendations to the full board of directors regarding) our overall compensation strategy and policies;

- reviewing and approving the compensation, the performance goals and objectives relevant to the compensation, and other terms of employment of our executive officers;
- reviewing and approving (or if it deems appropriate, making recommendations to the full board of directors regarding) the equity incentive plans, compensation plans and similar programs advisable for us, as well as modifying, amending or terminating existing plans and programs;
- reviewing and approving the terms of any employment agreements, severance arrangements, change in control protections and any other compensatory arrangements for our executive officers;
- reviewing with management and approving our disclosures under the caption "Compensation Discussion and Analysis" in our periodic reports or proxy statements to be filed with the SEC; and
- preparing the report that the SEC requires in our annual proxy statement.

Nominating and Corporate Governance Committee

Our nominating and corporate governance committee consists of Kimberly Murphy, who is the chair of the committee, Allan Shaw and James Sapirstein. Our board of directors has determined that each of the members of this committee satisfies the Nasdaq Marketplace Rules independence requirements. The functions of this committee include, among other things:

- identifying, reviewing and evaluating candidates to serve on our board of directors consistent with criteria approved by our board of directors;
- evaluating director performance on the board and applicable committees of the board and determining whether continued service on our board is appropriate;
- evaluating, nominating and recommending individuals for membership on our board of directors; and
- evaluating nominations by stockholders of candidates for election to our board of directors.

Scientific Advisory Board

In January 2020, we formally established a Scientific Advisory Board to advise our management regarding our clinical and regulatory development programs and other customary matters. Our scientific advisors are experts in various areas of medicine including theoretical epidemiology, vaccine research and development, and biotechnology. Our Scientific Advisory Board is comprised of the following individuals:

- Sunetra Gupta, Ph.D. Professor of Theoretical Epidemiology at The University of Oxford, a leading voice in infectious disease globally;
- David Zarley, Ph.D., with more than 30 years of experience in vaccine research and development, including former leadership roles at Pfizer and Wyeth; and,
- following the consummation of this offering, John Rice, Ph.D., Managing Director at CincyTech with more than 30 years of biotechnology advising experience.

Code of Business Conduct and Ethics

Prior to the consummation of this offering, our board of directors will adopt a written code of business conduct and ethics that applies to our directors, officers and employees, including our principal executive officer, principal financial officer, principal accounting officer or controller, or persons performing similar functions. We intend to post on our website a current copy of the code and all disclosures that are required by law or Nasdaq Marketplace Rules concerning any amendments to, or waivers from, any provision of the code.

Board Leadership Structure

Our board of directors is free to select the Chairman of the board of directors and the Chief Executive Officer in a manner that it considers to be in the best interests of our company at the time of selection. Currently, Mr. Joseph Hernandez serves as our Chief Executive Officer. Three of our five members of our board of directors have been deemed to be "independent" by the board of directors, which we believe provides sufficient independent oversight of our management. Because we have a non-executive Chairman of the board of directors, our board of directors has not designated a lead independent director.

Our board of directors, as a whole and also at the committee level, plays an active role overseeing the overall management of our risks. Our Audit Committee reviews risks related to financial and operational items with our management and our independent registered public accounting firm. Our board of directors is in regular contact with our Chief Executive Officer, who reports directly to the board of directors and who supervise day-to-day risk management.

Appointment Rights

Pursuant to our amended and restated certificate of incorporation as currently in effect prior to this offering, certain of our stockholders had rights to appoint members of our board of directors. Pursuant to these rights, of our current directors, Michael Venerable and John Rice were appointed by holders of our Series Seed Preferred Stock. These rights will terminate upon the consummation of this offering.

Role of Board in Risk Oversight Process

We face a number of risks, including those described under the caption "Risk Factors" contained elsewhere in this prospectus. Our board of directors believes that risk management is an important part of establishing, updating and executing on our business strategy. Our board of directors has oversight responsibility relating to risks that could affect the corporate strategy, business objectives, compliance, operations, and the financial condition and performance of our company. Our board of directors focuses its oversight on the most significant risks facing us and on our processes to identify, prioritize, assess, manage and mitigate those risks. Our board of directors receives regular reports from members of our senior management on areas of material risk to us, including strategic, operational, financial, legal and regulatory risks. While our board of directors has an oversight role, management is principally tasked with direct responsibility for management and assessment of risks and the implementation of processes and controls to mitigate their effects on us.

Potential Conflicts of Interest

Subject to certain non-compete restrictions, our chief executive officer, Joseph Hernandez, our chief financial officer following the offering, Jon Garfield and other key personnel may pursue other business or investment ventures while employed with us. Accordingly, they may have conflicts of interest in allocating time among various business activities and potentially competitive fiduciary and pecuniary interests that conflict with our interests. See "Risk Factors — Our Chief Executive Officer, Joseph Hernandez, and our Chief Financial Officer, Jon Garfield, hold certain management positions and directorships of other companies and may allocate their time to such other businesses, which may cause conflicts of interest in their determination as to how much time to devote to our affairs and potentially competitive fiduciary and pecuniary interests that conflict with our interests." For a complete discussion of the business affairs of our officers, directors and other personnel, please see "Management — Executive Officers and Directors." Any such additional business activities or ventures may present conflicts to our interests. We do not believe that any such potential conflicts would materially affect our ability to conduct our operations.

Our executive officers are supported by Ronald Cobb, Brian Price and Andrew Skibo, who provide valuable technical and strategic capabilities to us. They are not currently required to commit their full time to our affairs. As such, they may allocate their time to other businesses. From time to time, those other commitments may limit the nature of services that Messrs. Cobb, Price and Skibo provide to our Company, for instance, where such activities may involve overlapping industries and products. If these individuals' other business affairs require them to devote substantial amounts of time to such affairs in excess of their current commitment levels, it could limit their ability to devote time or resources to our affairs, which may have a negative impact on our ability to complete our plan of operations.

EXECUTIVE AND DIRECTOR COMPENSATION

The following table sets forth total compensation (prior to giving effect to the Pre-IPO Stock Split) paid to our named executive officers for the years ended December 31, 2020 and 2019. Individuals we refer to as our "named executive officers" include our Chief Executive Officer and our two other most highly compensated executive officers whose salary and bonus for services rendered in all capacities exceeded $100,000 during the fiscal year ended December 31, 2020.

Name and Principal Position	Year	Salary ($)	Bonus ($)	Option Awards ($)[2]	Non-Equity Incentive Plan Compensation ($)	Nonqualified Deferred Compensation Earnings ($)	All Other Compensation ($)	Total ($)
Joseph Hernandez	2020	420,000	—		—	—	—	420,000
Chief Executive Officer	2019	420,000	—	—	—	—	—	420,000
Brian Price	2020	122,979	—		—	—	3,500	126,479
Head of Technology Strategy	2019	83,333	—	1,480	—	—	—	84,813

(1) Mr. Price resigned from his position as Chief Operating Officer, effective as of August 15, 2020 and became a consultant for the Company.

(2) Consists of exercisable options to purchase 29,600 shares of common stock at an exercise price of $0.05 per share.

Employment Agreements of Named Executive Officers

We have entered or, upon the consummation of this offering, will enter into various employment agreements with certain of our executive officers. Set forth below is a summary of many of the material provisions of such agreements, which summaries do not purport to contain all of the material terms and conditions of each such agreement.

Joseph Hernandez

Effective upon the closing of this offering, we will enter into an employment agreement with Mr. Hernandez, pursuant to which he is employed as the Chief Executive Officer of the Company, which supersedes Mr. Hernandez's prior consulting agreement with the Company. The employment agreement provides for an annual base salary, subject to annual increases in the discretion of our compensation committee, the Company, and an annual performance bonus. Pursuant to the employment agreement, following the completion of this offering, Mr. Hernandez's base salary will be $595,000. The annual performance bonus will be up to 50% of annual base salary (the "Target Annual Bonus"), with the actual bonus being based upon the level of achievement of annual Company and individual performance objectives for such fiscal year, as determined by our compensation committee.

In the event that Mr. Hernandez's employment is terminated by the Company without cause (as defined in the employment agreement), or if Mr. Hernandez terminates his employment for "Good Reason" (as defined in the employment agreement), in addition to accrued unpaid salary, reimbursements and vacation days, he will be entitled to certain severance payments and benefits, including: (i) any unpaid annual bonus in respect of any completed fiscal year that has ended prior to the date of such termination; (ii) subject to certain conditions set forth in the employment agreement, an amount equal to (A) the Target Annual Bonus otherwise for the fiscal year in which such termination occurred, assuming Mr. Hernandez had remained employed through the applicable payment date, multiplied by (B) a fraction, the numerator of which is the number of days elapsed from the commencement of such fiscal year through the date of such termination and the denominator of which is 365 (or 366, as applicable); (iii) a payment equal to twelve (12) months of his base salary; and (iv) payment of an amount equal to the difference between the monthly COBRA premium cost and the monthly contribution paid by active employees for the same coverage for eighteen months following his termination. The employment agreement also provides that if a change in control (as defined in the employment agreement) occurs, and during the period commencing three months prior to a change in control and ending on the eighteen (18)-month anniversary of the change in control, Mr. Hernandez is terminated without cause or he resigns for good reason, Mr. Hernandez will be entitled to (i) any unpaid annual bonus in respect of any completed fiscal year that has ended prior to the date of such termination; (ii) subject to certain conditions set forth in the employment agreement, an amount equal to (A) the Target Annual Bonus

otherwise for the fiscal year in which such termination occurred, assuming Mr. Hernandez had remained employed through the applicable payment date, multiplied by (B) a fraction, the numerator of which is the number of days elapsed from the commencement of such fiscal year through the date of such termination and the denominator of which is 365 (or 366, as applicable); (iii) severance of 18 months' salary; and (iv) payment of an amount equal to the difference between the monthly COBRA premium cost and the monthly contribution paid by active employees for the same coverage for eighteen months following his termination. Additionally, all, any unvested portion of the equity awards held subject to time-vesting held by Mr. Hernandez will automatically vest.

The employment agreement is governed by the laws of the State of Delaware and contains non-solicitation and non-competition covenants (each of which remains in effect during the term of employment and for six months following termination of employment) and confidentiality, trade secrets and assignment of intellectual property clauses.

Pursuant to the non-solicitation and non-competition covenants, Mr. Hernandez has agreed to not directly or indirectly solicit any comparable business from a broad category of customers, request or advise customers to curtail, cancel, or withdraw its business from Blue Water Vaccines, Inc., aid any other entity in obtaining business from customers that is comparable or similar to any products or services provided by Blue Water Vaccines or otherwise interfere with any transaction, agreement, business relationship, and/or business opportunity between Blue Water Vaccines and any customer or potential customer of the Company.

During the term of employment and for a period of six months after termination ("the Post-Termination Restricted Period"), Mr. Hernandez is prohibited from recruiting, encouraging, soliciting, or inducing, or in any manner attempting to recruit, encourage, solicit, or induce, any person employed by or engaged by Blue Water Vaccines or its subsidiaries to terminate such Person's employment or services (or in the case of a consultant, materially reducing such services) with Blue Water Vaccines, Inc. or its subsidiaries, hiring, or engaging any individual who was employed by or providing services to Blue Water Vaccines, Inc. or its subsidiaries within the six (6) month period prior to the date of such hiring or engagement, or encouraging, soliciting, or inducing, or in any manner attempting to encourage, solicit, or induce, any current or prospective client, customer, licensee, supplier, or other business relation of Blue Water Vaccines, Inc. or its subsidiaries, or any such relation that was a client, customer, licensee or other business relationship within the prior six (6) month period to cease doing business with or reduce the amount of business conducted with Blue Water Vaccines, Inc. or its subsidiaries, or in any way interfering with the relationship between any such party and Blue Water Vaccines, Inc. or its subsidiaries.

Brian Price — Employment Agreement

On August 15, 2019, we entered into an employment agreement with Mr. Brian Price, which was subsequently superseded by the consultancy agreement described below, pursuant to which he was employed in the capacity of the Chief Operating Officer of the Company. The employment agreement was for a term of one (1) year, and was subject to automatic renewal for successive one (1) year terms upon the mutual agreement between Mr. Price and the Company. The employment agreement provided for an annual base salary of two hundred thousand dollars ($200,000), subject to an annual review by the Board of the Company. Additionally, the employment agreement contemplated: (a) an annual bonus of up to 30% of the base salary; (b) four (4) weeks of paid vacation during each calendar year, subject to the approval of the CEO; (c) reimbursement for medical insurance premiums of up to $2,000.00 per month, which was to continue until the Company offered comprehensive medical coverage (among others). Furthermore, the employment agreement contemplated an issuance of employee options to Mr. Price, equal to 2.5% of the then-available equity of the Company, under the terms of the Company's 2019 Equity Incentive Plan.

The employment agreement was terminable by the Company without cause (as defined in the employment agreement) or by Mr. Price for "Good Reason" (as defined in the employment agreement); and, in the event of such termination, the employment agreement entitled Mr. Price to receive any accrued unpaid salary, reimbursements and vacation days, as well as certain severance payments and benefits such as: a lump sum payment equal to six (6) months of base salary.

The employment agreement was governed by the laws of the State of New York, and contained non-solicitation and non-competition covenants (each of which remained in effect for the term of employment and for one (1) year following termination of employment), as well as confidentiality and non-disclosure, trade secrets and assignment of intellectual property clauses.

Brian Price — Consulting Agreement

On August 17, 2020, we entered into a consulting agreement with Mr. Brian Price, pursuant to which we retained Mr. Price's services as a consultant to the Company in the capacity of an "independent contractor" and not as an employee or agent of the Company. The term of the consulting agreement was one year and is subject to renewal by mutual agreement between Mr. Price and the Company. The Company and Mr. Price renewed the consulting agreement on August 16, 2021. Pursuant to the consulting agreement, Mr. Price's compensation includes an hourly rate of two hundred and fifty dollars ($250.00) for services provided to the Company, along with a reimbursement for all reasonable and necessary expenses incurred by Mr. Price in connection with, or related to, the performance of his services under the consulting agreement. Under the terms of the consulting agreement, Mr. Price is not entitled to any benefits, coverages or privileges available to employees of the Company, including, but not limited to: social security, unemployment, medical or pension payments.

The consulting agreement is terminable by the Company and by Mr. Price (without prejudice to any right or remedy that either may have due to a failure of the other to perform obligations under the terms of the consulting agreement) upon thirty (30) days' prior written notice. In the event of early termination, Mr. Price is entitled to payment for services performed and expenses paid or incurred prior to the effective date of the termination (subject to certain limitations on reimbursement of expenses, as defined in the consulting agreement). Additionally, if Mr. Price breaches or threatens a breach of certain provisions (defined in the consulting agreement), the Company may terminate the consulting agreement, effective immediately upon receipt of written notice.

The consulting agreement is governed by the laws of the State of Ohio, and contains non-solicitation and non-competition covenants (each of which remained in effect for the term of the consulting agreement and for one (1) year following the termination of the consulting agreement), as well as confidentiality and non-disclosure, trade secrets and assignment of intellectual property clauses. The consulting agreement requires that Mr. Price was not authorized to assume or create any obligation or responsibility (express or implied) on behalf of or in the name of the Company.

Potential Payments Upon Termination or Change-in-Control

See "Employment Agreements of Named Executive Officers" above.

Employee Benefit Plans

The principal features of our equity incentive plans are summarized below. These summaries are qualified in their entirety by reference to the actual text of the plans, which are filed as exhibits to the registration statement of which this prospectus forms a part.

2021 Equity Incentive Plan

Our board of directors adopted our 2021 Plan effective upon the completion of this offering, and we expect our stockholders to approve our 2021 Plan effective upon the completion of this offering. Our 2021 Plan is a successor to and continuation of our 2019 Plan. Our 2021 Plan will become effective on the date of the completion of this offering Once the 2021 Plan is effective, no further grants will be made under the 2019 Plan.

Awards. Our 2021 Plan provides for the grant of incentive stock options, or ISOs, within the meaning of Section 422 of the Internal Revenue Code, or the Code, to employees, including employees of any parent or subsidiary, and for the grant of nonstatutory stock options, or NSOs, stock appreciation rights, restricted stock awards, restricted stock unit awards, performance awards and other forms of awards to employees, directors and consultants, including employees and consultants of our affiliates.

Authorized Shares. Initially, the maximum number of shares of our common stock that may be issued under our 2021 Plan after it becomes effective will not exceed 1,600,000 shares of our common stock, which is the sum of (i) 200,000 new shares, plus (ii) an additional number of shares not to exceed 1,400,000, consisting of (A) shares that remain available for the issuance of awards under our 2019 Plan as of immediately prior to the time our 2021 Plan becomes effective and (B) shares of our common stock subject to outstanding stock options or other stock awards granted under our 2019 Plan that, on or after the 2021 Plan becomes effective, terminate or expire prior to exercise or settlement; are not issued because the award is settled in cash; are forfeited because of the failure to vest;

or are reacquired or withheld (or not issued) to satisfy a tax withholding obligation or the purchase or exercise price, if any, as such shares become available from time to time. The maximum number of shares of our common stock that may be issued on the exercise of ISOs under our 2021 Plan is 250,000 shares.

Shares subject to stock awards granted under our 2021 Plan that expire or terminate without being exercised in full or that are paid out in cash rather than in shares do not reduce the number of shares available for issuance under our 2021 Plan. Shares withheld under a stock award to satisfy the exercise, strike or purchase price of a stock award or to satisfy a tax withholding obligation do not reduce the number of shares available for issuance under our 2021 Plan. If any shares of our common stock issued pursuant to a stock award are forfeited back to or repurchased or reacquired by us (i) because of a failure to meet a contingency or condition required for the vesting of such shares, (ii) to satisfy the exercise, strike or purchase price of an award or (iii) to satisfy a tax withholding obligation in connection with an award, the shares that are forfeited or repurchased or reacquired will revert to and again become available for issuance under the 2010 Plan. Any shares previously issued which are reacquired in satisfaction of tax withholding obligations or as consideration for the exercise or purchase price of a stock award will again become available for issuance under the 2021 Plan.

Plan Administration. Our Board of Directors has assigned the authority to administer the 2021 Plan to our Compensation Committee, but may, at any time, re-vest in itself some or all of the power delegated to our Compensation Committee. The Compensation Committee may delegate to one or more of our officers the authority to (i) designate employees (other than officers) to receive specified stock awards and (ii) determine the number of shares subject to such stock awards. Under our 2021 Plan, our Compensation Committee has the authority to determine award recipients, grant dates, the numbers and types of stock awards to be granted, the applicable fair market value, and the provisions of each stock award, including the period of exercisability and the vesting schedule applicable to a stock award.

Stock Options. ISOs and NSOs are granted under stock option agreements in a form approved by the Compensation Committee. The Compensation Committee determines the exercise price for stock options, within the terms and conditions of the 2021 Plan, provided that the exercise price of a stock option generally cannot be less than 100% of the fair market value of our common stock on the date of grant. Options granted under the 2021 Plan vest at the rate specified in the stock option agreement as determined by the Compensation Committee.

The Compensation Committee determines the term of stock options granted under the 2021 Plan, up to a maximum of 10 years. Unless the terms of an option holder's stock option agreement, or other written agreement between us and the recipient approved by the Compensation Committee, provide otherwise, if an option holder's service relationship with us or any of our affiliates ceases for any reason other than disability, death or cause, the option holder may generally exercise any vested options for a period of three months following the cessation of service. This period may be extended in the event that exercise of the option is prohibited by applicable securities laws. If an option holder's service relationship with us or any of our affiliates ceases due to death, or an option holder dies within a certain period following cessation of service, the option holder or a beneficiary may generally exercise any vested options for a period of 18 months following the date of death. If an option holder's service relationship with us or any of our affiliates ceases due to disability, the option holder may generally exercise any vested options for a period of 12 months following the cessation of service. In the event of a termination for cause, options generally terminate upon the termination date. In no event may an option be exercised beyond the expiration of its term.

Acceptable consideration for the purchase of common stock issued upon the exercise of a stock option will be determined by the Compensation Committee and may include (i) cash, check, bank draft or money order, (ii) a broker-assisted cashless exercise, (iii) the tender of shares of our common stock previously owned by the option holder, (iv) a net exercise of the option if it is an NSO or (v) other legal consideration approved by the Board of Directors.

Unless the Compensation Committee provides otherwise, options or stock appreciation rights generally are not transferable except by will or the laws of descent and distribution. Subject to approval of the Compensation Committee or a duly authorized officer, an option may be transferred pursuant to a domestic relations order, official marital settlement agreement or other divorce or separation instrument.

Tax Limitations on ISOs. The aggregate fair market value, determined at the time of grant, of our common stock with respect to ISOs that are exercisable for the first time by an award holder during any calendar year under all of our stock plans may not exceed $100,000. Options or portions thereof that exceed such limit will generally be treated as NSOs. No ISO may be granted to any person who, at the time of the grant, owns or is deemed to own stock possessing more than 10% of our total combined voting power or that of any of our parent or subsidiary corporations unless (i) the option exercise price is at least 110% of the fair market value of the stock subject to the option on the date of grant and (ii) the term of the ISO does not exceed five years from the date of grant.

Restricted Stock Unit Awards. Restricted stock unit awards are granted under restricted stock unit award agreements in a form approved by the Compensation Committee. Restricted stock unit awards may be granted in consideration for any form of legal consideration that may be acceptable to our board of directors and permissible under applicable law. A restricted stock unit award may be settled by cash, delivery of stock, a combination of cash and stock as deemed appropriate by the Compensation Committee or in any other form of consideration set forth in the restricted stock unit award agreement. Additionally, dividend equivalents may be credited in respect of shares covered by a restricted stock unit award. Except as otherwise provided in the applicable award agreement, or other written agreement between us and the recipient approved by the Compensation Committee, restricted stock unit awards that have not vested will be forfeited once the participant's continuous service ends for any reason.

Restricted Stock Awards. Restricted stock awards are granted under restricted stock award agreements in a form approved by the Compensation Committee. A restricted stock award may be awarded in consideration for cash, check, bank draft or money order, past or future services to us or any other form of legal consideration that may be acceptable to our board of directors and permissible under applicable law. The Compensation Committee determines the terms and conditions of restricted stock awards, including vesting and forfeiture terms. If a participant's service relationship with us ends for any reason, we may receive any or all of the shares of common stock held by the participant that have not vested as of the date the participant terminates service with us through a forfeiture condition or a repurchase right.

Stock Appreciation Rights. Stock appreciation rights are granted under stock appreciation right agreements in a form approved by the Compensation Committee. The Compensation Committee determines the strike price for a stock appreciation right, which generally cannot be less than 100% of the fair market value of our common stock on the date of grant. A stock appreciation right granted under the 2021 Plan vests at the rate specified in the stock appreciation right agreement as determined by the Compensation Committee. Stock appreciation rights may be settled in cash or shares of common stock or in any other form of payment as determined by the Board and specified in the stock appreciation right agreement.

The Compensation Committee determines the term of stock appreciation rights granted under the 2021 Plan, up to a maximum of 10 years. If a participant's service relationship with us or any of our affiliates ceases for any reason other than cause, disability or death, the participant may generally exercise any vested stock appreciation right for a period of three months following the cessation of service. This period may be further extended in the event that exercise of the stock appreciation right following such a termination of service is prohibited by applicable securities laws. If a participant's service relationship with us, or any of our affiliates, ceases due to disability or death, or a participant dies within a certain period following cessation of service, the participant or a beneficiary may generally exercise any vested stock appreciation right for a period of 12 months in the event of disability and 18 months in the event of death. In the event of a termination for cause, stock appreciation rights generally terminate immediately upon the occurrence of the event giving rise to the termination of the individual for cause. In no event may a stock appreciation right be exercised beyond the expiration of its term.

Performance Awards. The 2021 Plan permits the grant of performance awards that may be settled in stock, cash or other property. Performance awards may be structured so that the stock or cash will be issued or paid only following the achievement of certain pre-established performance goals during a designated performance period. Performance awards that are settled in cash or other property are not required to be valued in whole or in part by reference to, or otherwise based on, the common stock.

The performance goals may be based on any measure of performance selected by the board of directors or the Compensation Committee. The performance goals may be based on company-wide performance or performance of one or more business units, divisions, affiliates or business segments, and may be either absolute or relative to the performance of one or more comparable companies or the performance of one or more relevant indices.

Unless specified otherwise by the board of directors at the time the performance award is granted, the board or Compensation Committee will appropriately make adjustments in the method of calculating the attainment of performance goals as follows: (i) to exclude restructuring and/or other nonrecurring charges; (ii) to exclude exchange rate effects; (iii) to exclude the effects of changes to generally accepted accounting principles; (iv) to exclude the effects of any statutory adjustments to corporate tax rates; (v) to exclude the effects of items that are "unusual" in nature or occur "infrequently" as determined under generally accepted accounting principles; (vi) to exclude the dilutive effects of acquisitions or joint ventures; (vii) to assume that any portion of our business which is divested achieved performance objectives at targeted levels during the balance of a performance period following such divestiture; (viii) to exclude the effect of any change in the outstanding shares of our common stock by reason of any stock dividend or split, stock repurchase, reorganization, recapitalization, merger, consolidation, spin-off, combination or exchange of shares or other similar corporate change or any distributions to common stockholders other than regular cash dividends; (ix) to exclude the effects of stock based compensation and the award of bonuses under our bonus plans; (x) to exclude costs incurred in connection with potential acquisitions or divestitures that are required to be expensed under generally accepted accounting principles; (xi) to exclude the goodwill and intangible asset impairment charges that are required to be recorded under generally accepted accounting principles; and (xi) to exclude the effects of the timing of acceptance for review and/or approval of submissions to the U.S. Food and Drug Administration or any other regulatory body.

Other Stock Awards. The Compensation Committee may grant other awards based in whole or in part by reference to our common stock. The Compensation Committee will set the number of shares under the stock award (or cash equivalent) and all other terms and conditions of such awards.

Non-Employee Director Compensation Limit. The aggregate value of all compensation granted or paid to any non-employee director with respect to any calendar year, including awards granted and cash fees paid by us to such non-employee director, will not exceed $150,000 in total value; provided that such amount will increase to $200,000 for the first year for newly appointed or elected non-employee directors.

Changes to Capital Structure. In the event there is a specified type of change in our capital structure, such as a stock split, reverse stock split or recapitalization, appropriate adjustments will be made to (i) the class and maximum number of shares reserved for issuance under the 2021 Plan, (ii) the class and maximum number of shares by which the share reserve may increase automatically each year, (iii) the class and maximum number of shares that may be issued on the exercise of ISOs and (iv) the class and number of shares and exercise price, strike price or purchase price, if applicable, of all outstanding stock awards.

Corporate Transactions. The following applies to stock awards under the 2021 Plan in the event of a corporate transaction (as defined in the 2021 Plan), unless otherwise provided in a participant's stock award agreement or other written agreement with us or one of our affiliates or unless otherwise expressly provided by the Board of Directors or Compensation Committee at the time of grant.

In the event of a corporate transaction, any stock awards outstanding under the 2021 Plan may be assumed, continued or substituted for by any surviving or acquiring corporation (or its parent company), and any reacquisition or repurchase rights held by us with respect to the stock award may be assigned to the successor (or its parent company). If the surviving or acquiring corporation (or its parent company) does not assume, continue or substitute for such stock awards, then (i) with respect to any such stock awards that are held by participants whose continuous service has not terminated prior to the effective time of the corporate transaction, or current participants, the vesting (and exercisability, if applicable) of such stock awards will be accelerated in full to a date prior to the effective time of the corporate transaction (contingent upon the effectiveness of the corporate transaction), and such stock awards will terminate if not exercised (if applicable) at or prior to the effective time of the corporate transaction, and any reacquisition or repurchase rights held by us with respect to such stock awards will lapse (contingent upon the effectiveness of the corporate transaction), and (ii) any such stock awards that are held by persons other than current participants will terminate if not exercised (if applicable) prior to the effective time of the corporate transaction, except that any reacquisition or repurchase rights held by us with respect to such stock awards will not terminate and may continue to be exercised notwithstanding the corporate transaction.

In the event a stock award will terminate if not exercised prior to the effective time of a corporate transaction, the board of directors may provide, in its sole discretion, that the holder of such stock award may not exercise such stock award but instead will receive a payment equal in value to the excess (if any) of (i) the per share amount payable to holders of common stock in connection with the corporate transaction over (ii) any per share exercise price payable by such holder, if applicable. In addition, any escrow, holdback, earn out or similar provisions in the definitive agreement for the corporate transaction may apply to such payment to the same extent and in the same manner as such provisions apply to the holders of common stock.

Plan Amendment or Termination. Our board of directors has the authority to amend, suspend or terminate our 2021 Plan, provided that such action does not materially impair the existing rights of any participant without such participant's written consent. Certain material amendments also require the approval of our stockholders. No ISOs may be granted after the tenth anniversary of the date our board of directors adopts our 2021 Plan. No stock awards may be granted under our 2021 Plan while it is suspended or after it is terminated.

2019 Equity Incentive Plan

Our board of directors adopted and our stockholders approved our 2019 Equity Incentive Plan (the "2019 Plan") in July 2019 for grants of awards to employees, directors, officers and consultants of us or any of our subsidiaries. Once the 2021 Plan is effective, no further grants will be made under the 2019 Plan. However, the 2019 Plan will continue to govern the terms and conditions of the outstanding awards previously granted under the 2019 Plan.

Awards. Our 2019 Plan provides for the grant of stock awards (collectively, "Stock Awards") to employees, directors, officers and consultants of us or any of our subsidiaries, consisting of (i) incentive stock options, ("ISOs"), within the meaning of Section 422 of the Internal Revenue Code (the "Code"); (ii) nonstatutory stock options ("NSOs"); (iii) stock appreciation rights; (iv) restricted stock awards; (v) restricted stock unit awards, and (vi) other forms of awards.

Authorized Shares. As of September 30, 2021, stock options covering 195,160 shares, each with an exercise price of $0.05 per share were the only outstanding Stock Awards outstanding under our 2019 Plan, and 154,840 shares of our common stock remained available for the future grant of awards under our 2019 Plan, which upon the adoption of the 2021 Plan, will become issuable under the 2021 Plan.

Plan Administration. The 2019 Plan may be administered by our board of directors, and our board of directors may delegate such administration to a committee of the board of directors (as applicable, the "Administrator"). The Administrator, in its discretion, selects the individuals to whom awards may be granted, the time or times at which such awards are granted and the terms and conditions of such awards.

Stock Options. Stock options entitle the holder to purchase a specified number of shares of common stock at a specified price (the exercise price), subject to the terms and conditions of the stock option grant. Our board of directors may grant either incentive stock options, which must comply with Code Section 422, or nonqualified stock options. ISO's may only be granted to employees of the Company or a "parent corporation" or "subsidiary corporation" thereof (as such terms are defined in Sections 424(e) and 424(f) of the Code). Our Administrator sets exercise prices and terms and conditions, except that stock options must be granted with an exercise price not less than 100% of the fair market value of our common stock on the date of grant. Unless our Administrator determines otherwise, fair market value means, as of a given date, the closing price of our common stock. At the time of grant, our board of directors determines the terms and conditions of stock options, including the quantity, exercise price, vesting periods, term (which may not exceed 10 years) and other conditions on exercise. Pursuant to the 2019 Plan, we may only issue 350,000 ISO's.

Eligibility. Awards may be granted under the 2019 Plan to officers, employees, directors, officers and of us and our subsidiaries. Incentive stock options may be granted only to employees of us or our subsidiaries.

Restricted Stock, Restricted Stock Units and Other Stock-Based Awards. Our board of directors may grant awards of restricted stock, which are shares of common stock subject to specified restrictions, and restricted stock units, or RSUs, which represent the right to receive shares of our common stock in the future. These awards may be made subject to repurchase, forfeiture or vesting restrictions at the discretion of our board of directors discretion. The restrictions may be based on continuous service with us or the attainment of specified performance goals, as

determined by the board of directors. Stock units may be paid in stock or cash or a combination of stock and cash, as determined by the board of directors. Other stock awards valued in whole or in part by reference to, or otherwise based on, Common Stock, including the appreciation in value thereof (e.g., options or stock rights with an exercise price or strike price less than one hundred percent (100%) of the fair market value of the common stock at the time of grant) may be granted either alone or in addition to stock awards provided for under the 2019 Plan.

Stock Appreciation Rights. Upon exercise, SARs entitle the holder to receive payment per share in stock or cash, or in a combination of stock and cash, equal to the excess of the share's fair market value on the date of exercise over the aggregate strike price of the number of Common Stock equivalents with respect to which the Participant is exercising the SAR on such date (the "grant price". Exercise of a SAR issued in tandem with a stock option will reduce the number of shares underlying the related stock option to the extent of the SAR exercised. The term of a SAR cannot exceed 10 years.

Changes to Capital Structure. In the event there is a specified type of change in our capital structure, such as a stock split, reverse stock split or recapitalization, appropriate adjustments will be made to (i) the class and maximum number of shares subject to the 2019 Plan, (ii) the class and maximum number of shares that may be issued on the exercise of ISOs and (iii) the class and number of shares and exercise price, strike price or purchase price, if applicable, of all outstanding stock awards.

Corporate Transactions. The following applies to Stock Awards under the 2019 Plan in the event of a corporate transaction (as defined in the 2019 Plan), unless otherwise provided in a participant's stock award agreement or other written agreement with us or one of our affiliates or unless otherwise expressly provided by the Board of Directors at the time of grant.

In the event of a corporate transaction, the board of directors may take one of the following actions, contingent on the completion of the corporate transaction: (i) arrange for the surviving or acquiring corporation (or its parent company) to assume, continue or substitute the Stock Award for a similar stock award; (ii) arrange for the assignment of any reacquisition or repurchase rights held by the Company in respect of common stock issued pursuant to the Stock Award to the surviving or acquiring corporation (or its parent company); (iii) accelerate the vesting (in whole or in part) of the Stock Award; (iv) arrange for the lapse, in whole or in part, of any reacquisition or repurchase rights held by the Company with respect to the Stock Award; (v) cancel or arrange for the cancellation of the Stock Award, to the extent not vested or not exercised prior to the effective time of the corporate transaction, in exchange for such cash consideration that the Board of Directors; and (vi) make a payment equal to the excess, if any, of (A) the value of the property the participant would have received upon the exercise of the Stock Award immediately prior to the effective time of the corporate transaction, over (B) any exercise price payable by such holder in connection with such exercise The Board of Directors need not take the same action or actions with respect to all Stock Awards or portions thereof or with respect to all participants. The Board of Directors may also take different actions with respect to the vested and unvested portions of a Stock Award.

Additionally, under the 2019 Plan, a Stock Award may be subject to additional acceleration of vesting and exercisability upon or after a Change in Control (as defined in the 2019 Plan) as may be provided in the Grant Agreement for such Stock Award or as may be provided in any other written agreement between the participant and the Company or any of its subsidiaries which may employ the participant, but in the absence of such provision, no such acceleration will occur.

Plan Amendment or Termination. Our board of directors has the authority to amend, suspend or terminate our 2019 Plan, subject to certain conditions, including that such action does not materially impair the existing rights of any participant without such participant's written consent. Certain material amendments also require the approval of our stockholders. No ISOs may be granted after the tenth anniversary of the date our board of directors adopted our 2019 Plan.

Limitation of Liability and Indemnification Matters

Our Amended and Restated Certificate of Incorporation and our Amended and Restated Bylaws, which will become effective in connection with this offering, limit our directors' liability, and may indemnify our directors and officers to the fullest extent permitted under Delaware General Corporation Law, or the DGCL. The DGCL provides that directors of a corporation will not be personally liable for monetary damages for breach of their fiduciary duties as directors, except for liability for any:

- transaction from which the director derives an improper personal benefit;
- act or omission not in good faith or that involves intentional misconduct or a knowing violation of law;
- unlawful payment of dividends or redemption of shares; or
- breach of a director's duty of loyalty to the corporation or its stockholders.

These limitations of liability do not apply to liabilities arising under federal securities laws and do not affect the availability of equitable remedies such as injunctive relief or recession.

The DGCL and our Amended and Restated Bylaws provide that we will, in certain situations, indemnify our directors and officers and may indemnify other employees and other agents, to the fullest extent permitted by law. Any indemnified person is also entitled, subject to certain limitations, to advancement, direct payment or reimbursement of reasonable expenses (including attorneys' fees and disbursements) in advance of the final disposition of the proceeding.

In addition, we have entered, and intend to continue to enter, into separate indemnification agreements with some of our directors and officers. These indemnification agreements, among other things, require us to indemnify our directors and officers for certain expenses, including attorneys' fees, judgments, fines and settlement amounts incurred by a director or officer in any action or proceeding arising out of their services as a director or officer, or any other company or enterprise to which the person provides services at our request.

We maintain a directors' and officers' insurance policy pursuant to which our directors and officers are insured against liability for actions taken in their capacities as directors and officers. We believe that these provisions in our Amended and Restated Certificate of Incorporation and Amended and Restated Bylaws and these indemnification agreements are necessary to attract and retain qualified persons as directors and officers.

Insofar as indemnification for liabilities arising under the Securities Act of 1933, as amended, or the Securities Act, may be permitted to directors, officers or control persons, in the opinion of the SEC, such indemnification is against public policy, as expressed in the Securities Act and is therefore unenforceable.

PRINCIPAL STOCKHOLDERS

The following table sets forth certain information concerning the ownership of our common stock as of September 30, 2021, with respect to: (i) each person, or group of affiliated persons, known to us to be the beneficial owner of more than five percent of our common stock; (ii) each of our directors; (iii) each of our named executive officers; and (iv) all of our current directors and executive officers as a group.

Applicable percentage ownership is based on 8,691,576 shares of common stock outstanding as of October 31, 2021 (after giving effect to (i) the conversion of all outstanding shares of convertible preferred stock and accrued dividends into an aggregate of 5,491,576 shares of common stock, pursuant to an optional conversion, effective upon consummation of this offering, which has been approved by requisite holders of our series seed preferred stock and (ii) the Pre-IPO Stock Split).

The percentage of beneficial ownership after this offering assumes the sale and issuance of shares of common stock in this offering and no exercise by the underwriters of their option to purchase additional shares of common stock.

We have determined beneficial ownership in accordance with the rules of the SEC. These rules generally attribute beneficial ownership of securities to persons who possess sole or shared voting or investment power with respect to such securities. In addition, pursuant to such rules, we deemed outstanding shares of common stock subject to options or warrants held by that person that are currently exercisable or exercisable within 60 days of October 31, 2021. We did not deem such shares outstanding, however, for the purpose of computing the percentage ownership of any other person. Except as indicated by the footnotes below, we believe, based on the information furnished to us, that the beneficial owners named in the table below have sole voting and investment power with respect to all shares of our common stock that they beneficially own, subject to applicable community property laws.

	Beneficial Ownership Prior to Offering		Beneficial Ownership After the Offering	
Name and Address of Beneficial Owner[1]	**Number of Shares**	**Percentage**	**Number of Shares**	**Percentage**
5% Stockholders				
Cincinnati Cornerstone Investors BWV I, LLC	3,524,692(1)	40.55%		
CincyTech Fund IV, LLC	808,744(2)	9.30%		
Named Executive Officers and Directors				
Joseph Hernandez	3,200,000	36.82%		
Kimberly Murphy	21,988(3)	*		
John Rice, Ph.D.	(3)	*		
Allan L. Shaw	21,988(3)	*		
Michael Venerable				
James Sapirstein				
Brian Price	43,992(4)	*		
All directors and named executive officers as a group (7 persons)		37.82%		

* Represents beneficial ownership of less than 1%.

(1) Consists of 3,524,692 shares of common stock (following the conversion of the preferred stock) held of record by Cincinnati Cornerstone Investors BWV I. Cincinnati Cornerstone Capital, LLC holds voting and dispositive power with respect to the shares of common stock held by Cincinnati Cornerstone Investors BWV I. The address for these entities is 2900 Reading Rd., Suite 410, Cincinnati, OH 45206.

(2) Consists of (i) 786,756 shares of common stock (following the conversion of preferred stock) held of record by CincyTech Fund IV, LLC and (ii) 21,988 shares of common stock underlying options that are currently exercisable within 60 days of October 31, 2021. CincyTech, LLC holds voting and dispositive power with respect to the shares of common stock held by CincyTech Fund IV, LLC. The address for these entities is 2900 Reading Rd., Suite 410, Cincinnati, OH 45206.

(3) Consists of 21,988 shares of common stock underlying options that are currently exercisable within 60 days of October 31, 2021.

(4) Consists of 43,992 shares of common stock underlying options that are currently exercisable within 60 days of October 31, 2021.

CERTAIN RELATIONSHIPS AND RELATED PARTY TRANSACTIONS

The following is a description of transactions since January 1, 2020 to which we were a party in which (i) the amount involved exceeded or will exceed the lesser of $120,000 of one percent (1%) of our average total assets at year-end for the last two completed fiscal years and (ii) any of our directors, executive officers or holders of more than 5% of our capital stock, or any member of the immediate family of, or person sharing the household with, any of the foregoing persons, who had or will have a direct or indirect material interest, other than equity and other compensation, termination, change in control and other similar arrangements, which are described under “Executive and Director Compensation.”

Equity Financings

Series Seed Preferred Stock Financing

In July 2019, we sold an aggregate of 1,146,138 shares of our Series Seed Preferred Stock, par value $0.00001 par value per share (the “Series Seed Stock”), at a purchase price of $6.09 per share for an aggregate purchase price of $6,979,980. The following table summarize purchases of our shares of Series Seed Stock by related persons, without taking into account the Pre-IPO Stock Split:

Stockholder	Number of Shares of Series Seed Preferred Stock	Total Purchase Price ($)
Cincinnati Cornerstone Investors BWV I, LLC	735,632	4,479,998.88
CincyTech Fund IV, LLC	164,203	999,996.27
Great American Insurance Company	82,101	499,995.09
Great American Life Insurance Company	82,101	499,995.09
John B. Berding Irrevocable Family Trust	82,101	499,995.09

Rights of Appointment

Our board of directors currently consists of five directors. Pursuant to our amended and restated certificate of incorporation in effect prior to this offering, certain of our stockholders, including our related parties, had rights to appoint members of our board of directors. See the section titled “Management — Appointment Rights.”

All rights to appoint directors will terminate upon the closing of this offering, although one currently serving director that was appointed prior to this offering will continue to serve pursuant to his appointment until the annual meeting of stockholders at which the term of their class of director expires.

Right of First Refusal and Co-Sale Agreement

We are party to a right of first refusal and co-sale agreement, pursuant to which we had a right to purchase (and certain other investors had the right to purchase in the case we did not exercise our right to purchase) shares of our capital stock which certain holders of our common stock propose to sell to other parties. The right of first refusal and co-sale agreement will terminate upon the completion of this offering.

Voting Agreement

We are party to a voting agreement under which certain holders of our capital stock have agreed as to the manner in which they will vote their shares of our capital stock on certain matters, including with respect to the election of directors.

The voting agreement will terminate upon the completion of this offering, at which time there will be no further contractual obligations regarding the manner in which shares are voted with respect to the election of our directors. Our directors hold office until their successors have been elected and qualified or until the earlier of their resignation or removal.

Other Transactions

Agreement with Blue Water Real Estate Holdings

We leased office space in November 28, 2018 from an affiliate of our chief executive officer, Blue Water Real Estate Holdings, Inc. Rental expense recorded for the years ended December 31, 2019, 2020, and through June 30, 2021 was $66,308, $66,308, and $27,628, respectively. This lease was terminated on March 31, 2021; however, the company did not vacate the premises until May 26, 2021. As of the effective date of the registration statement of which this prospectus forms a part, we have no outstanding obligations under this agreement.

Consulting Agreement with Joseph Hernandez

On October 22, 2018, we entered into a Consulting Agreement with Joseph Hernandez, the Chief Executive Officer of Blue Water Vaccines. Consulting expense recorded for the years ended December 31, 2019, 2020, and through June 30, 2021 was $420,000, $420,000, and $210,000, respectively. Pursuant to the Consulting Agreement, Joseph Hernandez provided us with consulting services, and we were required to pay an aggregate amount of $1.16 million to Joseph Hernandez. As of June 30, 2021, we are obligated to pay a total of $105,000.

Agreement with Blue Water Venture Partners

On October 22, 2018, we entered into a verbal agreement with Blue Water Venture Partners. Our CEO, Joe Hernandez, is the sole shareholder of Blue Water Ventures. Pursuant to the verbal agreement, Blue Water Venture Partners provided (i) the company's option fee to Oxford University Innovation, Ltd, (ii) a lease deposit to Blue Water Real Estate Holdings, Inc., (iii) purchased office furniture on behalf of the company and (iv) paid our rent for the period from November 28, 2019 through July 31, 2019. Expenses recorded for the year ended December 31, 2019, 2020 and through June 30, 2021 were $35,000, $0 and $0, respectively. We were required to pay an aggregate amount of $89,617 to Blue Water Venture Partners. As of the effective date of the registration statement of which this prospectus forms a part, we have no outstanding obligations under this agreement.

Indemnification of Officers and Directors

Our Amended and Restated Certificate of Incorporation and Amended and Restated Bylaws, which will become effective in connection with this offering, will provide that we will indemnify each of our directors and officers to the fullest extent permitted by the DGCL. Further, we intend to enter into indemnification agreements with each of our directors and officers, and we have purchased a policy of directors' and officers' liability insurance that insures our directors and officers against the cost of defense, settlement or payment of a judgment under certain circumstances. For further information, see "Executive and Director Compensation — Limitations of Liability and Indemnification Matters."

Policies and Procedures for Related Party Transactions

All future transactions between us and our officers, directors or five percent stockholders, and respective affiliates will be on terms no less favorable than could be obtained from unaffiliated third parties and will be approved by a majority of our independent directors who do not have an interest in the transactions and who had access, at our expense, to our legal counsel or independent legal counsel.

To the best of our knowledge, during the past two fiscal years, other than as set forth above, there were no material transactions, or series of similar transactions, or any currently proposed transactions, or series of similar transactions, to which we were or are to be a party, in which the amount involved exceeds $120,000, and in which any director or executive officer, or any security holder who is known by us to own of record or beneficially more than 5% of any class of our common stock, or any member of the immediate family of any of the foregoing persons, has an interest (other than compensation to our officers and directors in the ordinary course of business).

DESCRIPTION OF CAPITAL STOCK

The following is a summary of the rights of our common stock and preferred stock, certain provisions of our Amended and Restated Certificate of Incorporation and our Amended and Restated Bylaws as they will be in effect following this offering 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

Upon completion of this offering, our authorized capital stock will consist of 150,000,000 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 October 31, 2021 (after giving effect to (i) the conversion of all outstanding shares of convertible preferred stock and accrued dividends, pursuant to an optional conversion, effective upon consummation of this offering, which has been approved by requisite holders of our series seed preferred stock, into an aggregate of up 5,491,576 shares of common stock and (ii) the Pre-IPO Stock Split), there were 8,691,576 shares of common stock issued and outstanding, no shares of common stock issuable upon exercise of outstanding warrants, and 780,640 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.

Preferred Stock

Upon the closing of this offering, we will have no shares of preferred stock designated or outstanding, but our board of directors will be authorized, without further action by the stockholders, to establish one or more class or series, and fix the relative rights and preferences of the company’s undesignated capital stock.

Options

As of October 31, 2021 (after giving effect to (i) the conversion of all outstanding shares of convertible preferred stock and accrued dividends, pursuant to an optional conversion, effective upon consummation of this offering, which has been approved by requisite holders of our series seed preferred stock, into an aggregate of up 5,491,576 shares of common stock and (ii) the Pre-IPO Stock Split), we had outstanding options to purchase an aggregate 780,640 shares of our common stock, each with an exercise price of $0.20 per share.

Warrants

We have no outstanding warrants to purchase our common stock prior to the consummation of this offering.

Representative's Warrants

We have agreed to sell to the representative of the underwriters of this offering, or its permitted designees, for nominal consideration, warrants to purchase 111,111 shares of our common stock (or up to 127,778, depending on the extent to which the underwriters' option to purchase additional shares is exercised) as additional consideration to the underwriters in this offering. The underwriters' warrants will have an exercise price equal to 115% of the public offering price in this offering and shall be exercisable for a period of five years following the commencement of sales in this offering and will contain customary "cashless" exercise and registration rights provisions. The warrants shall not be exercisable for a period of six months from the date of effectiveness of the registration statement of which this prospectus forms a part. For more about these warrants see the section titled Underwriting — Representative's Warrants.

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 $66^{2}/_{3}$% 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 will:

- 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 $66^{2}/_{3}$% 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 $66^{2}/_{3}$% 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 to be adopted in connection with this offering will provide will require, 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 will provide 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

We intend to apply to list our common stock 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.

SHARES ELIGIBLE FOR FUTURE SALE

Prior to this offering, no public market existed for our common stock. Future sales of substantial amounts of our common stock in the public market following this offering, or the possibility of such sales occurring, could adversely affect prevailing market prices and could impair our ability to raise capital through the offering of equity securities.

Based on the number of shares of common stock outstanding as of September 30, 2021 (after giving effect to (i) the conversion of all outstanding shares of convertible preferred stock and accrued dividends, pursuant to an optional conversion, effective upon consummation of this offering, which has been approved by requisite holders of our series seed preferred stock, into an aggregate of up 5,491,576 shares of common stock and (ii) the Pre-IPO Stock Split), upon the completion of this offering, we will have a total of 10,913,798 shares of common stock outstanding, assuming an initial public offering price of $9.00 per share and assuming no exercise by the underwriters of their option to purchase additional shares of common stock and no exercise of outstanding options or warrants to purchase shares of common stock. All of the shares sold in this offering will be freely tradable unless held by our “affiliates”, as defined in Rule 144 under the Securities Act.

As a result of contractual restrictions described below and the provisions of Rules 144 and 701 promulgated under the Securities Act, the shares of common stock sold in this offering will be available for sale in the public market as follows:

- all the shares of common stock sold in this offering will be eligible for immediate sale upon the closing of this offering; and
- common shares will be eligible for sale in the public market upon expiration of lock-up agreements 180 days after the date of this prospectus, subject, in certain circumstances to the volume, manner of sale and other limitations under Rule 144 and Rule 701.

Rule 144

In general, persons (or persons whose shares are required to be aggregated) who have beneficially owned shares of our common stock for at least six months, and any affiliate of ours who owns shares of our common stock, are entitled to sell their securities without registration with the SEC under an exemption from registration provided by Rule 144 under the Securities Act.

Non-Affiliates

Any person (or persons whose shares are required to be aggregated) who is not deemed to have been an affiliate of ours at any time during the three months preceding a sale, and who has beneficially owned restricted securities for at least six months, including the holding period of any prior owner other than one of our affiliates, is entitled to sell those shares, subject only to the availability of current public information about us and provided that we have been subject to the Exchange Act periodic reporting requirements for at least 90 days before the sale. If such person has held our shares for at least one year, such person can resell such shares under Rule 144(b)(1) without regard to any Rule 144 restrictions, including the 90-day public company and current public information requirements.

Affiliates

Any person (or persons whose shares are required to be aggregated) who is deemed to be an affiliate of ours and who has beneficially owned restricted securities within the meaning of Rule 144 for at least six months would be subject to the restrictions described above. Additionally, such person would be subject to additional restrictions, pursuant to which such person would be required to comply with the manner of sale and notice provisions of Rule 144 and would be entitled to sell within any three-month period a number of shares that does not exceed the greater of:

- 1% of the number of shares of common stock then outstanding, which will equal 109,137 shares immediately after this offering, based on the number of shares outstanding as of October 31, 2021 and assuming, (i) the conversion of all outstanding shares of convertible preferred stock and accrued dividends, pursuant to an optional conversion, effective upon consummation of this offering, which has been approved by requisite

holders of our series seed preferred stock, into an aggregate of up 5,491,576 shares of common stock and (ii) the Pre-IPO Stock Split and (iii) no exercise by the underwriters of their option to purchase additional shares of common stock and no outstanding options or warrants; or

- the average weekly trading volume of our shares of common stock on the Nasdaq Capital Market during the four calendar weeks preceding the filing of a notice on Form 144 with respect to such sale.

Additionally, persons who are our affiliates at the time of, or any time during the three months preceding, a sale may sell unrestricted securities under the requirements of Rule 144 described above, without regard to the six-month holding period of Rule 144, which does not apply to sales of unrestricted securities.

Rule 701

Under Rule 701 under the Securities Act, shares of our common stock acquired upon the exercise of currently outstanding options or pursuant to other rights granted under our stock plans may be resold, by:

- persons other than affiliates, beginning 90 days after the effective date of the registration statement of which this prospectus forms a part, subject only to the manner-of-sale provisions of Rule 144; and
- our affiliates, beginning 90 days after the effective date of the registration statement of which this prospectus forms a part, subject to the manner-of-sale and volume limitations, current public information and filing requirements of Rule 144, in each case, without compliance with the six-month holding period requirement of Rule 144.

Notwithstanding the foregoing, all our Rule 701 shares are subject to lock-up agreements as described below and in the section titled “Underwriting” and will become eligible for sale upon the expiration of the restrictions set forth in those agreements.

Lock-Up Agreements

We and our directors, officers any other holder(s) of three percent (3.0%) or more of our outstanding common stock as of the effective date of the Registration Statement which this prospectus forms a part of (and all holders of securities exercisable for or convertible into three percent (3.0%) or more of our common stock) have entered into customary “lock-up” agreements in favor of Maxim pursuant to which such persons and entities have agreed, for a period of six (6) months after the effective date of the registration statement related to this offering, that they shall neither offer, issue, sell, contract to sell, encumber, grant any option for the sale of or otherwise dispose of any securities of the Company without Maxim’s prior written consent, including the issuance of shares of common stock upon the exercise of currently outstanding options approved by Maxim.

Form S-8 Registration Statement

We intend to file a registration statement on Form S-8 under the Securities Act after the closing of this offering to register the shares of our common stock that are issuable pursuant to our 2021 Plan. The registration statement is expected to be filed and become effective as soon as practicable after the completion of this offering. Accordingly, shares registered under such registration statement will be available for sale in the open market following its effective date, subject to Rule 144 volume limitations and the lock-up arrangement described above, if applicable.

UNDERWRITING

We are offering our common stock described in this prospectus through the underwriter named below. Maxim Group LLC, or Maxim or the representative, is acting as representative of the underwriter. We have entered into an underwriting agreement with the underwriter. Subject to the terms and conditions of the underwriting agreement, the underwriter has agreed to purchase, and we have agreed to sell to the underwriter, the number of common stock listed next to its name in the following table.

Underwriter	Number of Shares
Maxim Group LLC	
Total	

The underwriting agreement provides that the underwriter must buy all of the shares of common stock being sold in this offering if they buy any of them. However, the underwriter is not required to take or pay for the shares of common stock covered by the underwriter's option to purchase additional common stock as described below.

Our common stock are offered subject to a number of conditions, including:

- receipt and acceptance of our common stock by the underwriter; and
- the underwriter's right to reject orders in whole or in part.

We have been advised by Maxim that the underwriter intends to make a market in our common stock but that it is not obligated to do so and may discontinue making a market at any time without notice.

In connection with this offering, the underwriter or securities dealers may distribute prospectuses electronically.

Option to Purchase Additional Common Stock

We have granted the representative an option to buy up to an aggregate of additional shares of common stock. The representative has 45 days from the date of this prospectus to exercise this option. If the representative exercises this option, it will purchase additional shares of common stock approximately in proportion to the amounts specified in the table above.

Underwriting Discount

Shares sold by the representative to the public will initially be offered at the initial offering price set forth on the cover of this prospectus. Any shares sold by the representative to securities dealers may be sold at a discount of up to $ per share from the initial public offering price. The representative may offer the shares through one or more of their affiliates or selling agents. If all the shares are not sold at the initial public offering price, the representative may change the offering price and the other selling terms. Upon execution of the underwriting agreement, the representative will be obligated to purchase the shares at the prices and upon the terms stated therein.

We have agreed to pay the underwriters a cash fee equal to eight percent (8.0%) of the aggregate gross proceeds from the sale of the common stock, provided however, that the discount or spread shall be three and one half percent (3.5%) for any investors initially introduced by us, so long as such investors do not require the services of Maxim registered representatives in connection with their participation in the offering (collectively, the "Company Investors").

The following table summarizes the public offering price, underwriting commissions and proceeds before expenses to us assuming both no exercise and full exercise of the underwriters' option to purchase additional common stock.

	Per Share	Total without Over-Allotment Option	Total with Over-Allotment Option
Public offering price	$	$	$
Underwriting discounts and commissions	$	$	$
Proceeds, before expenses to us	$	$	$

We have agreed to pay Maxim's out-of-pocket accountable expenses, including Maxim's legal fees, up to a maximum amount of $125,000 if this offering is completed. We are required to pay $25,000 to Maxim as an advance to be applied towards reasonable out-of-pocket expenses, or the Advance. Any portion of the Advance shall be returned back to us to the extent not actually incurred.

We estimate that the total expenses of the offering payable by us, not including the underwriting discount, will be approximately $. We have also agreed to reimburse the underwriter for certain expenses incurred by them.

Representative's Warrants

We have also agreed to issue to Maxim (or its permitted assignees) warrants to purchase 111,111 shares (or up to 127,778 shares, depending on the extent to which the underwriters' option to purchase additional shares is exercised) of our common stock, which is equal to an aggregate of 5% of the total number of common stock sold in this offering, excluding Shares sold to existing Company stockholders, or the representative's warrants. The representative's warrants will have an exercise price equal to $10.35 (115% of the offering price of the common stock sold in this offering) and may be exercised on a cashless basis. The representative's warrants are exercisable commencing six months after the effective date of the registration statement related to this offering, and will expire five years after such date. The representative's warrants are not redeemable by us. We have agreed to a one-time demand registration of the shares of common stock underlying the representative's warrants at our expense for a period of five years from the effective date of the registration statement related to this offering. The representative's warrants also provide for unlimited "piggyback" registration rights at our expense with respect to the underlying common stock during the five-year period commencing from the effective date of the registration statement related to this offering. The representative's warrants and the common stock underlying the representative's warrants, have been deemed compensation by the Financial Industry Regulatory Authority, or FINRA, and are therefore subject to a 180-day lock-up pursuant to Rule 5110(g)(1) of FINRA. Maxim (or permitted assignees under the Rule) may not sell, transfer, assign, pledge or hypothecate the representative's warrants or the securities underlying the representative's warrants, nor will they engage in any hedging, short sale, derivative, put or call transaction that would result in the effective economic disposition of the representative's warrants or the underlying securities for a period of six months from the effective date of this offering, except to any FINRA member participating in the offering and their bona fide officers or partners. The representative's warrants will provide for adjustment in the number and price of such representative's warrants (and the common stock underlying such representative's warrants) to prevent dilution in the event of a forward or reverse stock split, stock dividend or similar recapitalization.

Right of First Refusal

We have agreed to grant Maxim, for the period commencing on the effective date of the registration statement related to this offering and concluding fifteen (15) months thereafter, a right of first refusal to act as sole underwriter or placement agent for any and all future public and private equity and debt (excluding commercial bank debt) offerings of the Company, or any successor to or any subsidiary of the Company during such fifteen (15) month period, except for financing provided by or solicited from any person or entity who is a current holder of the Company's debt or equity.

Lock-Up Agreements

We and our directors, officers any other holder(s) of three percent (3.0%) or more of our outstanding common stock as of the effective date of the Registration Statement which this prospectus forms a part of (and all holders of securities exercisable for or convertible into three percent (3.0%) or more of our common stock) have entered into customary "lock-up" agreements in favor of Maxim pursuant to which such persons and entities have agreed, for a period of six (6) months after the effective date of the registration statement related to this offering, that they

shall neither offer, issue, sell, contract to sell, encumber, grant any option for the sale of or otherwise dispose of any securities of the Company without Maxim's prior written consent, including the issuance of shares of common stock upon the exercise of currently outstanding options approved by Maxim.

Indemnification

We have agreed to indemnify the underwriter against certain liabilities, including certain liabilities under the Securities Act. If we are unable to provide this indemnification, we have agreed to contribute to payments the underwriter may be required to make in respect of those liabilities.

Other Relationships

The underwriter and its affiliates have engaged in, and may in the future engage in, investment banking and other commercial dealings in the ordinary course of business with us or our affiliates. They have received, or may in the future receive, customary fees and commissions for these transactions.

No Public Market

Prior to this offering, there has not been a public market for our securities in the U.S. and the public offering price for our common stock will be determined through negotiations between us and the underwriter. Among the factors to be considered in these negotiations will be prevailing market conditions, our financial information, market valuations of other companies that we and the underwriter believe to be comparable to us, estimates of our business potential, the present state of our development and other factors deemed relevant.

We offer no assurances that the initial public offering price will correspond to the price at which our common stock will trade in the public market subsequent to this offering or that an active trading market for our common stock will develop and continue after this offering.

Stock Exchange

We intend to apply to list our common stock on the Nasdaq Capital Market, under the symbol "BWV" There can be no assurance that we will be successful in listing our common stock on the Nasdaq Capital Market.

Electronic Distribution

A prospectus in electronic format may be made available on websites or through other online services maintained by the underwriter of this offering, or by their affiliates. Other than the prospectus in electronic format, the information on any underwriter's website and any information contained in any other website maintained by an underwriter is not part of this prospectus or the registration statement of which this prospectus forms a part, has not been approved and/or endorsed by us or any underwriter in its capacity as underwriter, and should not be relied upon by investors.

Price Stabilization, Short Positions

In connection with this offering, the underwriter may engage in activities that stabilize, maintain or otherwise affect the price of our common stock during and after this offering, including:

- stabilizing transactions;
- short sales;
- purchases to cover positions created by short sales;
- imposition of penalty bids; and
- syndicate covering transactions.

Stabilizing transactions consist of bids or purchases made for the purpose of preventing or retarding a decline in the market price of our common stock while this offering is in progress. Stabilization transactions permit bids to purchase the underlying security so long as the stabilizing bids do not exceed a specified maximum. These

transactions may also include making short sales of our common stock, which involve the sale by the underwriter of a greater number of common stock than they are required to purchase in this offering and purchasing common stock on the open market to cover short positions created by short sales. Short sales may be "covered short sales," which are short positions in an amount not greater than the underwriter's option to purchase additional shares referred to above, or may be "naked short sales," which are short positions in excess of that amount.

The underwriter may close out any covered short position by either exercising their option, in whole or in part, or by purchasing shares in the open market. In making this determination, the underwriter will consider, among other things, the price of shares available for purchase in the open market as compared to the price at which they may purchase shares through the over-allotment option.

Naked short sales are short sales made in excess of the over-allotment option. The underwriter must close out any naked short position by purchasing shares in the open market. A naked short position is more likely to be created if the underwriter is concerned that there may be downward pressure on the price of the common stock in the open market that could adversely affect investors who purchased in this offering.

The underwriter also may impose a penalty bid. This occurs when a particular underwriter repays to the underwriter a portion of the underwriting discount received by it because Maxim has repurchased shares sold by or for the account of that underwriter in stabilizing or short covering transactions.

These stabilizing transactions, short sales, purchases to cover positions created by short sales, the imposition of penalty bids and syndicate covering transactions may have the effect of raising or maintaining the market price of our common stock or preventing or retarding a decline in the market price of our common stock. As a result of these activities, the price of our common stock may be higher than the price that otherwise might exist in the open market. The underwriter may carry out these transactions on the Nasdaq Capital Market, in the over-the-counter market or otherwise. Neither we nor the underwriter make any representation or prediction as to the effect that the transactions described above may have on the price of the shares. Neither we, nor the underwriter make any representation that the underwriter will engage in these stabilization transactions or that any transaction, once commenced, will not be discontinued without notice.

Determination of Offering Price

Prior to this offering, there was no public market for our common stock. The initial public offering price will be determined by negotiation between us and Maxim. The principal factors to be considered in determining the initial public offering price include, but not limited to:

- the information set forth in this prospectus and otherwise available to Maxim;
- our history and prospects and the history and prospects for the industry in which we compete;
- our past and present financial performance;
- our prospects for future earnings and the present state of our development;
- the general condition of the securities market at the time of this offering;
- the recent market prices of, and demand for, publicly traded shares of generally comparable companies; and
- other factors deemed relevant by the underwriter and us.

The estimated public offering price range set forth on the cover page of this preliminary prospectus is subject to change as a result of market conditions and other factors. Neither we nor the underwriter can assure investors that an active trading market will develop for our common stock or that the common stock will trade in the public market at or above the initial public offering price.

Affiliations

The underwriter and its respective affiliates are full service financial institutions engaged in various activities, which may include securities trading, commercial and investment banking, financial advisory, investment

management, investment research, principal investment, hedging, financing and brokerage activities. The underwriter and its affiliates may from time to time in the future engage with us and perform services for us or in the ordinary course of their business for which they will receive customary fees and expenses. In the ordinary course of their various business activities, the underwriter and its respective affiliates may make or hold a broad array of investments and actively trade debt and equity securities (or related derivative securities) and financial instruments (including bank loans) for their own account and for the accounts of their customers, and such investment and securities activities may involve securities and/or instruments of us. The underwriter and its respective affiliates may also make investment recommendations and/or publish or express independent research views in respect of these securities or instruments and may at any time hold, or recommend to clients that they acquire, long and/or short positions in these securities and instruments.

Offer Restrictions Outside the United States

No action has been taken in any jurisdiction (except in the United States) that would permit a public offering of the common stock the possession, circulation or distribution of this prospectus or any other material relating to us or the common stock in any jurisdiction where action for that purpose is required. Accordingly, the common stock may not be offered or sold, directly or indirectly, and neither this prospectus nor any other material or advertisements in connection with the common stock may be distributed or published, in or from any country or jurisdiction except in compliance with any applicable laws, rules and regulations of any such country or jurisdiction.

Australia. This prospectus:

- does not constitute a product disclosure document or a prospectus under Chapter 6D.2 of the Corporations Act 2001 (Cth) (the "Corporations Act");
- has not been, and will not be, lodged with the Australian Securities and Investments Commission ("ASIC"), as a disclosure document for the purposes of the Corporations Act and does not purport to include the information required of a disclosure document under Chapter 6D.2 of the Corporations Act;
- does not constitute or involve a recommendation to acquire, an offer or invitation for issue or sale, an offer or invitation to arrange the issue or sale, or an issue or sale, of interests to a "retail client" (as defined in section 761G of the Corporations Act and applicable regulations) in Australia; and
- may only be provided in Australia to select investors who are able to demonstrate that they fall within one or more of the categories of investors, or Exempt Investors, available under section 708 of the Corporations Act.

The common stock may not be directly or indirectly offered for subscription or purchased or sold, and no invitations to subscribe for or buy the common stock may be issued, and no draft or definitive offering memorandum, advertisement or other offering material relating to any common stock may be distributed in Australia, except where disclosure to investors is not required under Chapter 6D of the Corporations Act or is otherwise in compliance with all applicable Australian laws and regulations. By submitting an application for the common stock, you represent and warrant to us that you are an Exempt Investor.

As any offer of common stock under this prospectus will be made without disclosure in Australia under Chapter 6D.2 of the Corporations Act, the offer of those securities for resale in Australia within 12 months may, under section 707 of the Corporations Act, require disclosure to investors under Chapter 6D.2 if none of the exemptions in section 708 applies to that resale. By applying for the common stock, you undertake to us that you will not, for a period of 12 months from the date of issue of the common stock, offer, transfer, assign or otherwise alienate those securities to investors in Australia except in circumstances where disclosure to investors is not required under Chapter 6D.2 of the Corporations Act or where a compliant disclosure document is prepared and lodged with ASIC.

This prospectus contains general information only and does not take account of the investment objectives, financial situation or particular needs of any particular person. It does not contain any securities recommendations or

financial product advice. Before making an investment decision, investors need to consider whether the information in this prospectus is appropriate to their needs, objectives and circumstances, and, if necessary, seek expert advice on those matters.

Canada. The common stock may be sold only to purchasers purchasing, or deemed to be purchasing, as principal that are accredited investors, as defined in National Instrument 45-106 Prospectus Exemptions or subsection 73.3(1) of the Securities Act (Ontario), and are permitted clients, as defined in National Instrument 31-103 Registration Requirements, Exemptions and Ongoing Registrant Obligations. Any resale of the common stock must be made in accordance with an exemption from, or in a transaction not subject to, the prospectus requirements of applicable securities laws.

Securities legislation in certain provinces or territories of Canada may provide a purchaser with remedies for rescission or damages if this prospectus (including any amendment thereto) contains a misrepresentation, provided that the remedies for rescission or damages are exercised by the purchaser within the time limit prescribed by the securities legislation of the purchaser's province or territory. The purchaser should refer to any applicable provisions of the securities legislation of the purchaser's province or territory for particulars of these rights or consult with a legal advisor.

Pursuant to section 3A.3 of National Instrument 33-105 Underwriting Conflicts (NI 33-105), the underwriter is not required to comply with the disclosure requirements of NI 33-105 regarding underwriter conflicts of interest in connection with this offering.

Cayman Islands. This prospectus does not constitute a public offer of the common stock, whether by way of sale or subscription, in the Cayman Islands. Common stock have not been offered or sold, and will not be offered or sold, directly or indirectly, in the Cayman Islands.

Dubai International Financial Centre ("DIFC"). This prospectus relates to an Exempt Offer in accordance with the Markets Rules 2012 of the Dubai Financial Services Authority (the "DFSA"). This prospectus is intended for distribution only to persons of a type specified in the Markets Rules 2012 of the DFSA. It must not be delivered to, or relied on by, any other person. The DFSA has no responsibility for reviewing or verifying any documents in connection with Exempt Offers. The DFSA has not approved this prospectus supplement nor taken steps to verify the information set forth herein and has no responsibility for this prospectus. The securities to which this prospectus relates may be illiquid and/or subject to restrictions on their resale. Prospective purchasers of the securities offered should conduct their own due diligence on the securities. If you do not understand the contents of this prospectus you should consult an authorized financial advisor.

In relation to its use in the DIFC, this prospectus is strictly private and confidential and is being distributed to a limited number of investors and must not be provided to any person other than the original recipient, and may not be reproduced or used for any other purpose. The interests in the securities may not be offered or sold directly or indirectly to the public in the DIFC.

European Economic Area. In relation to each Member State of the European Economic Area which has implemented the Prospectus Directive (each, a Relevant Member State), with effect from and including the date on which the Prospectus Directive was implemented in that Relevant Member State (the Relevant Implementation Date), an offer of the common stock to the public may not be made in that Relevant Member State prior to the publication of a prospectus in relation to the common stock which has been approved by the competent authority in that Relevant Member State or, where appropriate, approved in another Relevant Member State and notified to the competent authority in that Relevant Member State, all in accordance with the Prospectus Directive, except that, with effect from and including the Relevant Implementation Date, an offer of common stock may be made to the public in that Relevant Member State at any time:

- to any legal entity which is a qualified investor as defined under the Prospectus Directive;
- to fewer than 100 or, if the Relevant Member State has implemented the relevant provision of the 2010 PD Amending Directive, 150 natural or legal persons (other than qualified investors as defined in the Prospectus Directive); or
- in any other circumstances falling within Article 3(2) of the Prospectus Directive, provided that no such offer of securities described in this prospectus shall result in a requirement for the publication by us of a prospectus pursuant to Article 3 of the Prospectus Directive.

For the purposes of the above paragraph, the expression “an offer of the common stock to the public” in relation to any common stock in any Relevant Member State means the communication in any form and by any means of sufficient information on the terms of the offer and the common stock to be offered so as to enable an investor to decide to purchase or subscribe the common stock, as the same may be varied in that Member State by any measure implementing the Prospectus Directive in that Member State. The expression Prospectus Directive means Directive 2003/71/EC (and any amendments thereto, including the 2010 PD Amending Directive, to the extent implemented in the Relevant Member State) and includes any relevant implementing measure in each Relevant Member State, and the expression “2010 PD Amending Directive” means Directive 2010/73/EU.

Hong Kong. The common stock may not be offered or sold by means of any document other than (i) in circumstances which do not constitute an offer to the public within the meaning of the Companies Ordinance (Cap.32, Laws of Hong Kong), (ii) to “professional investors” within the meaning of the Securities and Futures Ordinance (Cap.571, Laws of Hong Kong) and any rules promulgated thereunder, or (iii) in other circumstances which do not result in the document being a “prospectus” within the meaning of the Companies Ordinance (Cap.32, Laws of Hong Kong), and no advertisement, invitation or document relating to the common stock may be issued or may be in the possession of any person for the purpose of issue (in each case whether in Hong Kong or elsewhere), which is directed at, or the contents of which are likely to be accessed or read by, the public in Hong Kong (except if permitted to do so under the laws of Hong Kong) other than with respect to common stock which are or are intended to be disposed of only to persons outside Hong Kong or only to “professional investors” within the meaning of the Securities and Futures Ordinance (Cap. 571, Laws of Hong Kong) and any rules promulgated thereunder.

Japan. Common stock have not been and will not be registered under the Financial Instruments and Exchange Law of Japan (Law No. 25 of 1948, as amended) and, accordingly, will not be offered or sold directly or indirectly in Japan or to, or for the benefit of any Japanese person or to others, for re-offering or re-sale directly or indirectly in Japan or to any Japanese person, except in each case pursuant to an exemption from the registration requirements of, and otherwise in compliance with, the Securities and Exchange Law of Japan and any other applicable laws, rules and regulations of Japan. For purposes of this paragraph, “Japanese person” means any person resident in Japan, including any corporation or other entity organized under the laws of Japan.

Kuwait. Unless all necessary approvals from the Kuwait Ministry of Commerce and Industry required by Law No. 31/1990 “Regulating the Negotiation of Securities and Establishment of Investment Funds,” its Executive Regulations and the various Ministerial Orders issued pursuant thereto or in connection therewith, have been given in relation to the marketing and sale of the common stock, these may not be marketed, offered for sale, nor sold in the State of Kuwait. Neither this prospectus (including any related document), nor any of the information contained therein is intended to lead to the conclusion of any contract of whatsoever nature within Kuwait.

Malaysia. No prospectus or other offering material or document in connection with the offer and sale of the common stock has been or will be registered with the Securities Commission of Malaysia (the “Commission”) for the Commission’s approval pursuant to the Capital Markets and Services Act 2007. Accordingly, this prospectus and any other document or material in connection with the offer or sale, or invitation for subscription or purchase, of the common stock may not be circulated or distributed, nor may the common stock be offered or sold, or be made the subject of an invitation for subscription or purchase, whether directly or indirectly, to persons in Malaysia other than (i) a closed end fund approved by the Commission; (ii) a holder of a Capital Markets Services License; (iii) a person who acquires the common stock , as principal, if the offer is on terms that the common stock may only be acquired at a consideration of not less than RM250,000 (or its equivalent in foreign currencies) for each transaction; (iv) an individual whose total net personal assets or total net joint assets with his or her spouse exceeds RM3 million (or its equivalent in foreign currencies), excluding the value of the primary residence of the individual; (v) an individual who has a gross annual income exceeding RM300,000 (or its equivalent in foreign currencies) per annum in the preceding twelve months; (vi) an individual who, jointly with his or her spouse, has a gross annual income of RM400,000 (or its equivalent in foreign currencies), per annum in the preceding twelve months; (vii) a corporation with total net assets exceeding RM10 million (or its equivalent in a foreign currencies) based on the last audited accounts; (viii) a partnership with total net assets exceeding RM10 million (or its equivalent in foreign currencies); (ix) a bank licensee or insurance licensee as defined in the Labuan Financial Services and Securities Act 2010; (x) an Islamic bank licensee or takaful licensee as defined in the Labuan Financial Services and Securities Act 2010; and (xi) any other person as may be specified by the Commission; provided that, in the each of the preceding categories (i) to (xi), the distribution of the common stock is made by a holder of a Capital Markets Services License who carries on the business of dealing in securities. The distribution in Malaysia of this prospectus is subject to

Malaysian laws. This prospectus does not constitute and may not be used for the purpose of public offering or an issue, offer for subscription or purchase, invitation to subscribe for or purchase any securities requiring the registration of a prospectus with the Commission under the Capital Markets and Services Act 2007.

People's Republic of China. This prospectus may not be circulated or distributed in the PRC and the common stock may not be offered or sold, and will not offer or sell to any person for re-offering or resale directly or indirectly to any resident of the PRC except pursuant to applicable laws, rules and regulations of the PRC. For the purpose of this paragraph only, the PRC does not include Taiwan and the special administrative regions of Hong Kong and Macau.

Qatar. In the State of Qatar, the offer contained herein is made on an exclusive basis to the specifically intended recipient thereof, upon that person's request and initiative, for personal use only and shall in no way be construed as a general offer for the sale of securities to the public or an attempt to do business as a bank, an investment company or otherwise in the State of Qatar. This prospectus and the underlying securities have not been approved or licensed by the Qatar Central Bank or the Qatar Financial Centre Regulatory Authority or any other regulator in the State of Qatar. The information contained in this prospectus shall only be shared with any third parties in Qatar on a need to know basis for the purpose of evaluating the contained offer. Any distribution of this prospectus by the recipient to third parties in Qatar beyond the terms hereof is not permitted and shall be at the liability of such recipient.

Saudi Arabia. This prospectus may not be distributed in the Kingdom of Saudi Arabia except to such persons as are permitted under the Offers of Securities Regulations issued by the Capital Market Authority. The Capital Market Authority does not make any representation as to the accuracy or completeness of this prospectus, and expressly disclaims any liability whatsoever for any loss arising from, or incurred in reliance upon, any part of this prospectus. Prospective purchasers of the securities offered hereby should conduct their own due diligence on the accuracy of the information relating to the securities. If you do not understand the contents of this prospectus you should consult an authorized financial adviser.

Singapore. This prospectus or any other offering material relating to the common stock has not been registered as a prospectus with the Monetary Authority of Singapore under the Securities and Futures Act, Chapter 289 of Singapore, or the SFA. Accordingly, (a) the common stock have not been, and will not be, offered or sold or made the subject of an invitation for subscription or purchase of such common stock in Singapore, and (b) this prospectus or any other document or material in connection with the offer or sale, or invitation for subscription or purchase, of the common stock have not been and will not be circulated or distributed, whether directly or indirectly, to the public or any member of the public in Singapore other than (i) to an institutional investor as specified in Section 274 of the SFA, (ii) to a relevant person (as defined in Section 275 of the SFA) and in accordance with the conditions specified in Section 275 of the SFA or (iii) otherwise pursuant to, and in accordance with the conditions of, any other applicable provision of the SFA.

Where the common stock are subscribed or purchased under Section 275 of the SFA by a relevant person which is:

(a) a corporation (which is not an accredited investor (as defined in Section 4A of the SFA)) the sole business of which is to hold investments and the entire share capital of which is owned by one or more individuals, each of whom is an accredited investor; or

(b) a trust (where the trustee is not an accredited investor) whose sole purpose is to hold investments and each beneficiary of the trust is an individual who is an accredited investor, securities (as defined in Section 239(1) of the SFA) of that corporation or the beneficiaries' rights and interest (howsoever described) in that trust shall not be transferred within six months after that corporation or that trust has acquired the common stock pursuant to an offer made under Section 275 of the SFA except:

(a) to an institutional investor or to a relevant person defined in Section 275(2) of the SFA, or to any person arising from an offer referred to in Section 275(1A) or Section 276(4)(i)(B) of the SFA;

(b) where no consideration is or will be given for the traIer;

(c) where the transfer is by operation of law;

(d) as specified in Section 276(7) of thIFA; or

(e) as specified in Regulation 32 of the Securities and Futures (Offers of Investments) (Shares and Debentures) Regulations 2005 of Singapore.

Switzerland. The common stock will not be publicly offered in Switzerland and will not be listed on the SIX Swiss Exchange, or SIX, or on any other stock exchange or regulated trading facility in Switzerland. This prospectus has been prepared without regard to the disclosure standards for issuance prospectuses under art. 652a or art. 1156 of the Swiss Code of Obligations or the disclosure standards for listing prospectuses under art. 27 ff. of the SIX Listing Rules or the listing rules of any other stock exchange or regulated trading facility in Switzerland. Neither this prospectus nor any other offering or marketing material relating to our company or the common stock have been or will be filed with or approved by any Swiss regulatory authority. In particular, this prospectus will not be filed with, and the offer of the common stock will not be supervised by, the Swiss Financial Market Supervisory Authority, and the offer of the common stock has not been and will not be authorized under the Swiss Federal Act on Collective Investment Schemes (the "CISA"). The investor protection afforded to acquirers of interests in collective investment schemes under the CISA does not extend to acquirers of the common stock.

Taiwan. The common stock have not been and will not be registered with the Financial Supervisory Commission of Taiwan pursuant to relevant securities laws and regulations and may not be sold, issued or offered within Taiwan through a public offering or in circumstances which constitutes an offer within the meaning of the Securities and Exchange Act of Taiwan that requires a registration or approval of the Financial Supervisory Commission of Taiwan. No person or entity in Taiwan has been authorized to offer, sell, give advice regarding or otherwise intermediate the offering and sale of the common stock in Taiwan.

United Arab Emirates. The common stock have not been offered or sold, and will not be offered or sold, directly or indirectly, in the United Arab Emirates, except: (i) in compliance with all applicable laws and regulations of the United Arab Emirates; and (ii) through persons or corporate entities authorized and licensed to provide investment advice and/or engage in brokerage activity and/or trade in respect of foreign securities in the United Arab Emirates. The information contained in this prospectus does not constitute a public offer of securities in the United Arab Emirates in accordance with the Commercial Companies Law (Federal Law No. 8 of 1984 (as amended)) or otherwise and is not intended to be a public offer and is addressed only to persons who are sophisticated investors.

United Kingdom. This prospectus is only being distributed to and is only directed at, and any offer subsequently made may only be directed at: (i) persons who are outside the United Kingdom; (ii) investment professionals falling within Article 19(5) of the Financial Services and Markets Act 2000 (Financial Promotion) Order 2005 (the "Order"); or (iii) high net worth companies, and other persons to whom it may lawfully be communicated, falling within Article 49(2)(a) to (d) of the Order (all such persons falling within (1)-(3) together being referred to as "relevant persons"). The common stock are only available to, and any invitation, offer or agreement to subscribe, purchase or otherwise acquire the common stock will be engaged in only with, relevant persons. Any person who is not a relevant person should not act or rely on this prospectus or any of its contents.

Vietnam. This offering of common stock has not been and will not be registered with the State Securities Commission of Vietnam under the Law on Securities of Vietnam and its guiding decrees and circulars.

LEGAL MATTERS

The validity of the shares of common stock and representative's warrants offered hereby will be passed upon for us by Ellenoff Grossman & Schole LLP, New York, New York. Certain legal matters will be passed upon for the underwriters by Loeb & Loeb LLP, New York, New York.

EXPERTS

The financial statements of Blue Water Vaccines, Inc. as of and for the years ended December 31, 2020 and 2019 included in this registration statement, of which this prospectus forms a part, have been audited by Mayer Hoffman McCann P.C., independent registered public accounting firm, as set forth in their report (which includes an explanatory paragraph related to the existence of substantial doubt about the Company's ability to continue as a going concern) appearing elsewhere herein, and are included in reliance upon such report given on the authority of such firm as experts in auditing and accounting in giving said report.

WHERE YOU CAN FIND MORE INFORMATION

We have filed with the SEC a registration statement on Form S-1 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.

BLUE WATER VACCINES, INC.

INDEX TO FINANCIAL STATEMENTS

Report of Independent Registered Public Accounting Firm

To the Board of Directors and Stockholders of
Blue Water Vaccines, Inc.

Opinion on the Financial Statements

We have audited the accompanying balance sheets of **Blue Water Vaccines, Inc**. (the "Company") as of December 31, 2020 and 2019, and the related statements of operations, stockholders' equity, and cash flows for each of the two years in the period ended December 31, 2020, and the related notes (collectively referred to as the "financial statements"). In our opinion, the financial statements present fairly, in all material respects, the financial position of the Company as of December 31, 2020 and 2019, and the results of its operations and its cash flows for each of the two years in the period ended December 31, 2020, in conformity with accounting principles generally accepted in the United States of America.

Going Concern Uncertainty

The accompanying financial statements have been prepared assuming that the Company will continue as a going concern. As discussed in Note 2 to the financial statements, the Company has incurred recurring losses and negative cash flows from operations and is dependent on additional financing to fund operations. These conditions raise substantial doubt about its ability to continue as a going concern. Management's plans regarding these matters are also described in Note 2. The financial statements do not include any adjustments that might result from the outcome of this uncertainty.

Basis for Opinion

These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on the Company's financial statements based on our audits. We are a public accounting firm registered with the Public Company Accounting Oversight Board (United States) ("PCAOB") and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audits in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audits to obtain reasonable assurance about whether the financial statements are free of material misstatement, whether due to error or fraud. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. As part of our audits, we are required to obtain an understanding of internal control over financial reporting but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion.

Our audits included performing procedures to assess the risks of material misstatement of the financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the financial statements. Our audits also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the financial statements. We believe that our audits provide a reasonable basis for our opinion.

We have served as the Company's auditor since 2021.

/s/ Mayer Hoffman McCann P.C.

Los Angeles, California
August 20, 2021

BLUE WATER VACCINES, INC.
Balance Sheets

	June 30, 2021	December 31, 2020	December 31, 2019
	(Unaudited)		
ASSETS			
Current assets			
Cash	$ 3,669,468	$ 4,308,821	$ 6,050,751
Prepaid expenses and other current assets	355,353	277,853	8
Deferred offering cost	30,000	—	—
Receivable from related party	22,242	9,805	8,330
Total current assets	4,077,063	4,596,479	6,059,089
Prepaid expenses	92,467	184,934	—
Property and equipment, net	13,189	15,667	6,931
Deposit	—	15,000	15,000
Total assets	**$ 4,182,719**	**$ 4,812,080**	**$ 6,081,020**
LIABILITIES AND STOCKHOLDERS' EQUITY			
Current liabilities			
Accounts payable	$ 55,631	$ 68,668	$ 18,377
Accrued expenses	434,728	—	57,385
Total current liabilities	490,359	68,668	75,762
Deferred rent	—	9,642	6,859
Total liabilities	**490,359**	**78,310**	**82,621**
Stockholders' equity			
Preferred stock, $0.00001 par value, 1,150,000 shares authorized;			
Series Seed: 1,150,000 shares designated; 1,146,138 shares issued and outstanding at June 30, 2021 and December 31, 2020 and 2019; $8.1 million, $7.8 million and $7.3 million aggregate liquidation preference of Series Seed cumulative preferred stock at June 30, 2021 and December 31, 2020 and 2019, respectively	11	11	11
Common stock, $0.00001 par value, 2,300,000 shares authorized; 800,000 shares outstanding at June 30, 2021 and December 31, 2020 and 2019	8	8	8
Additional paid-in-capital	7,349,732	7,273,087	6,938,250
Accumulated deficit	(3,657,391)	(2,539,336)	(939,870)
Total stockholders' equity	3,692,360	4,733,770	5,998,399
Total liabilities and stockholders' equity	**$ 4,182,719**	**$ 4,812,080**	**$ 6,081,020**

The accompanying notes are an integral part of these financial statements.

BLUE WATER VACCINES, INC.
Statements of Operations

	Six months ended June 30, 2021	Six months ended June 30, 2020	Year Ended December 31, 2020	Year Ended December 31, 2019
	(Unaudited)	(Unaudited)		
Operating costs and expenses				
General and administrative	$ 500,276	$ 559,775	$ 1,097,161	$ 820,058
Research and development	617,779	320,336	524,908	60,174
Total operating expenses	1,118,055	880,111	1,622,069	880,232
Loss from operations	(1,118,055)	(880,111)	(1,622,069)	(880,232)
Other income				
Interest income	—	19,431	22,603	58,317
Total other income	—	19,431	22,603	58,317
Net loss	**$ (1,118,055)**	**$ (860,680)**	**$ (1,599,466)**	**$ (821,915)**
Cumulative preferred stock dividends	276,904	278,434	559,928	279,964
Net loss applicable to common stockholders	(1,394,959)	(1,139,114)	(2,159,394)	(1,101,879)
Net loss per share attributable to common stockholders, basic and diluted	$ (1.74)	$ (1.42)	$ (2.70)	$ (1.38)
Weighted average number of common shares outstanding, basic and diluted	800,000	800,000	800,000	800,000

The accompanying notes are an integral part of these financial statements.

BLUE WATER VACCINES, INC.
Statements of Stockholders' Equity

For the Years Ended December 31, 2020 and 2019

	Preferred Stock		Common Stock		Additional Paid-in Capital	Accumulated Deficit	Total Stockholders' Equity
	Shares	Amount	Shares	Amount			
Balance at December 31, 2018	**—**	**$ —**	**800,000**	**$ 8**	**$ —**	**$ (117,955)**	**$ (117,947)**
Issuance of Series Seed Preferred stock to investors (net of issuance cost of $44,985)	1,146,138	11	—	—	6,934,984	—	6,934,995
Stock-based compensation	—	—	—	—	3,266	—	3,266
Net loss	—	—	—	—	—	(821,915)	(821,915)
Balance at December 31, 2019	**1,146,138**	**$ 11**	**800,000**	**$ 8**	**$ 6,938,250**	**$ (939,870)**	**$ 5,998,399**
Stock-based compensation	—	—	—	—	334,837	—	334,837
Net loss	—	—	—	—	—	(1,599,466)	(1,599,466)
Balance at December 31, 2020	**1,146,138**	**$ 11**	**800,000**	**$ 8**	**$ 7,273,087**	**$ (2,539,336)**	**$ 4,733,770**

For the Six Months Ended June 30, 2021

	Preferred Stock		Common Stock		Additional Paid-in Capital	Accumulated Deficit	Total Stockholders' Equity
	Shares	Amount	Shares	Amount			
Balance at December 31, 2020	**1,146,138**	**$ 11**	**800,000**	**$ 8**	**$ 7,273,087**	**$ (2,539,336)**	**$ 4,733,770**
Stock-based compensation (Unaudited)	—	—	—	—	76,645	—	76,645
Net loss (Unaudited)	—	—	—	—	—	(1,118,055)	(1,118,055)
Balance at June 30, 2021 (Unaudited)	**1,146,138**	**$ 11**	**800,000**	**$ 8**	**$ 7,349,732**	**$ (3,657,391)**	**$ 3,692,360**

For the Six Months Ended June 30, 2020

	Preferred Stock		Common Stock		Additional Paid-in Capital	Accumulated Deficit	Total Stockholders' Equity
	Shares	Amount	Shares	Amount			
Balance at December 31, 2019	**1,146,138**	**$ 11**	**800,000**	**$ 8**	**$ 6,938,250**	**$ (939,870)**	**$ 5,998,399**
Stock-based compensation (Unaudited)	—	—	—	—	235,810	—	235,810
Net loss (Unaudited)	—	—	—	—	—	(860,680)	(860,680)
Balance at June 30, 2020 (Unaudited)	**1,146,138**	**$ 11**	**800,000**	**$ 8**	**$ 7,174,060**	**$ (1,800,550)**	**$ 5,373,529**

The accompanying notes are an integral part of these financial statements.

BLUE WATER VACCINES, INC.
Statements of Cash Flows

	Six months ended June 30, 2021	Six months ended June 30, 2020	Year Ended December 31, 2020	Year Ended December 31, 2019
	(Unaudited)	(Unaudited)		
Cash flows from operating activities				
Net loss	$ (1,118,055)	$ (860,680)	$ (1,599,466)	$ (821,915)
Adjustments to reconcile net loss to net cash used in operating activities:				
Depreciation expense	2,478	1,195	3,056	573
Stock-based compensation	76,645	235,810	334,837	3,266
Changes in assets and liabilities:				
Prepaid expenses and other assets	(77,500)	(378,282)	(277,845)	—
Deferred offering cost	(30,000)	—	—	—
Receivable from related party	(12,437)	—	(1,475)	(8,330)
Prepaid expenses	92,467	(184,934)	(184,934)	—
Deposit	15,000	—	—	—
Accrued expenses	434,728	(57,385)	(57,385)	(22,905)
Accounts payable	(13,037)	(7,932)	50,291	18,377
Deferred rent	(9,642)	—	2,783	5,808
Net cash used in operating activities	(639,353)	(1,252,208)	(1,730,138)	(825,126)
Cash flows from investing activities				
Purchase of property and equipment	—	(6,027)	(11,792)	(4,500)
Net cash used in investing activities	—	(6,027)	(11,792)	(4,500)
Cash flows from financing activities				
Repayment of loan from related party	—	—	—	(54,617)
Proceeds from issuance of Series Seed Preferred stock to investors (net of issuance cost of $44,985)	—	—	—	6,934,994
Net cash provided by financing activities	—	—	—	6,880,377
Net (decrease) increase in cash	(639,353)	(1,258,235)	(1,741,930)	6,050,751
Cash, beginning of period	4,308,821	6,050,751	6,050,751	—
Cash, end of period	$ 3,669,468	$ 4,792,516	$ 4,308,821	$ 6,050,751

The accompanying notes are an integral part of these financial statements.

BLUE WATER VACCINES, INC.
Notes to Financial Statements

Note 1 — Organization, Plan of Business Operations

Blue Water Vaccines, Inc. (the "Company") was formed on October 26, 2018, to focus on the research and development of transformational vaccines to prevent infectious diseases worldwide. The Company's lead vaccine candidates, BWV-101 and BWV-102, are being investigated as a universal influenza vaccine with the potential against all influenza strains and may provide a first-in-class long-term global vaccine that protects millions. The Company's proprietary, immunogenic, multi-purpose platform enables the Company to bioengineer viral nanoparticles to deliver antigens, enhancing immunity, in an array of infectious disease agents, including influenza. All of the Company's vaccine candidates are in the pre-clinical developmental stage.

Note 2 — Liquidity, Financial Condition and Management's Plans

The Company has had limited operating activities to date, substantially all of which have been devoted to seeking licenses and engaging in research and development activities. The Company's product candidates currently under development will require significant additional research and development efforts prior to commercialization. The Company has financed its operations since inception primarily using proceeds received from seed investors.

The Company has incurred substantial operating losses since inception and expects to continue to incur significant operating losses for the foreseeable future. As of June 30, 2021, the Company had cash of approximately $3.7 million, working capital of approximately $3.6 million and an accumulated deficit of approximately $3.7 million.

The Company will require significant additional capital to sustain its short-term operations and make the investments it needs to execute its longer-term business plan. The Company believes the existing cash at June 30, 2021, will be sufficient to continue operations, satisfy its obligations and fund the future expenditures that will be required to conduct the clinical and regulatory work to develop its product candidates until the second quarter of 2022. The Company is currently seeking to obtain additional debt or equity financing, however, there are currently no commitments in place for further financing nor is there any assurance that such financing will be available to the Company on favorable terms, if at all. If the Company is unable to secure additional capital, it may be required to curtail any clinical trials and development of products and take additional measures to reduce expenses in order to conserve its cash in amounts sufficient to sustain operations and meet its obligations.

Because of operating losses and a net operating cash flow deficit, there is substantial doubt about the Company's ability to continue as a going concern for one year from the issuance of the financial statements, which is not alleviated by management's plans. The financial statements have been prepared assuming the Company will continue as a going concern. These financial statements do not include any adjustments that might be necessary from the outcome of this uncertainty.

Note 3 — Summary of Significant Accounting Policies

Basis of Presentation

The Company's financial statements have been prepared in conformity with accounting principles generally accepted in the United States of America ("U.S. GAAP").

Unaudited Interim Financial Statements

The accompanying balance sheet as of June 30, 2021, and the statements of operations, the statements of changes in stockholders' equity, and the statements of cash flows for the six months ended June 30, 2021 and 2020 are unaudited. These unaudited interim financial statements have been prepared on the same basis as the audited financial statements, and in management's opinion, include all adjustments, consisting of only normal recurring adjustments, necessary for the fair statement of the Company's financial position as of June 30, 2021 and its results of operations and cash flows for the six months ended June 30, 2021 and 2020. The financial data and the other financial information disclosed in the notes to these financial statements related to the six-month periods are also unaudited. Operating results for the period for the six months ended June 30, 2021 are not necessarily indicative of the results that may be expected through December 31, 2021.

BLUE WATER VACCINES, INC.
Notes to Financial Statements

Note 3 — Summary of Significant Accounting Policies (cont.)

Use of Estimates

The preparation of financial statements in conformity with U.S. GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of expenses during the reporting periods. The most significant estimates in the Company's financial statements relate to the valuation of common stock, stock-based compensation, accrued research and development expenses and the valuation allowance of deferred tax assets resulting from net operating losses. These estimates and assumptions are based on current facts, historical experience and various other factors believed to be reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities and the recording of expenses that are not readily apparent from other sources. Actual results may differ materially and adversely from these estimates. To the extent there are material differences between the estimates and actual results, the Company's future results of operations will be affected.

Concentration of Credit Risk

Financial instruments that potentially subject the Company to concentrations of credit risk consist of cash accounts in a financial institution, which, at times, may exceed the Federal Depository Insurance Coverage limit of $250,000. As of June 30, 2021, December 31, 2020 and 2019, the Company has not experienced losses on these accounts and management believes the Company is not exposed to significant risks on such accounts.

Property and Equipment

Property and equipment consists of leasehold improvements, computer, equipment and office furniture and fixtures, all of which are recorded at cost. Depreciation and amortization is recorded using the straight-line method over the respective useful lives of the assets ranging from three to five years. Long-lived assets are reviewed for impairment whenever events or circumstances indicate that the carrying amount of these assets may not be recoverable.

Fair Value of Financial Instruments

Financial instruments, including cash, accounts payable and accrued liabilities are carried at cost, which management believes approximates fair value due to the short-term nature of these instruments. The fair value of the Company's assets and liabilities, which qualify as financial instruments under the Financial Accounting Standards Board ("FASB") Accounting Standards Codification ("ASC") Topic 820, *Fair Value Measurements*, approximates the carrying amounts represented in the balance sheet.

Fair Value Measurements

Fair value is defined as the price that would be received for sale of an asset or paid for transfer of a liability, in an orderly transaction between market participants at the measurement date. U.S. GAAP establishes a three-tier fair value hierarchy, which prioritizes the inputs used in measuring fair value. The hierarchy gives the highest priority to unadjusted quoted prices in active markets for identical assets or liabilities (Level 1 measurements) and the lowest priority to unobservable inputs (Level 3 measurements). These tiers include:

- Level 1, defined as observable inputs such as quoted prices (unadjusted) for identical instruments in active markets;
- Level 2, defined as inputs other than quoted prices in active markets that are either directly or indirectly observable such as quoted prices for similar instruments in active markets or quoted prices for identical or similar instruments in markets that are not active; and

BLUE WATER VACCINES, INC.
Notes to Financial Statements

Note 3 — Summary of Significant Accounting Policies (cont.)

- Level 3, defined as unobservable inputs in which little or no market data exists, therefore requiring an entity to develop its own assumptions, such as valuations derived from valuation techniques in which one or more significant inputs or significant value drivers are unobservable.

In some circumstances, the inputs used to measure fair value might be categorized within different levels of the fair value hierarchy. In those instances, the fair value measurement is categorized in its entirety in the fair value hierarchy based on the lowest level input that is significant to the fair value measurement.

Deferred offering costs

Deferred offering costs consist of legal, accounting, and other costs incurred through the balance sheet date that are directly related to the proposed initial public offering and that will be charged to stockholders' equity upon the completion of the proposed initial public offering. Should the proposed initial public offering prove to be unsuccessful, these deferred costs, as well as additional expenses to be incurred, will be charged to operations.

Research and Development

The Company expenses the cost of research and development as incurred. Research and development expenses include costs incurred in funding research and development activities, license fees, and other external costs. Advance payments for goods and services that will be used in future research and development activities are expensed when the activity has been performed or when the goods have been received rather than when the payment is made. Upfront and milestone payments due to third parties that perform research and development services on the Company's behalf will be expensed as services are rendered or when the milestone is achieved.

In accordance with FASB ASC Topic 730-10-25-1, *Research and Development*, costs incurred in obtaining licenses and patent rights are charged to research and development expense if the technology licensed has not reached commercial feasibility and has no alternative future use. The licenses purchased by the Company (see Note 5) require substantial completion of research and development, regulatory and marketing approval efforts to reach commercial feasibility and has no alternative future use. Accordingly, the total purchase price for the licenses acquired is reflected as research and development on the Company's statements of operations.

Stock-Based Compensation

The Company expensed stock-based compensation to employees and non-employees over the requisite service period based on the estimated grant-date fair value of the awards. Stock-based awards to employees with graded-vesting schedules are recognized, using the accelerated attribution method, on a straight-line basis over the requisite service period for each separately vesting portion of the award. Changes in the estimated fair value of awards are recognized as compensation expense in the period of change.

The Company estimates the fair value of stock option grants using the Black-Scholes option pricing model and the assumptions used in calculating the fair value of stock-based awards represent management's best estimates and involve inherent uncertainties and the application of management's judgment.

Expected Term — The expected term of options represents the period that the Company's stock-based awards are expected to be outstanding based on the simplified method, which is the half-life from vesting to the end of its contractual term.

Expected Volatility — The Company computes stock price volatility over expected terms based on comparable companies historical common stock trading prices.

Common Stock Fair Value — The fair value of the common stock underlying the Company's stock options was estimated at each grant date and was determined with the assistance of an independent third-party valuation expert. The assumptions underlying these valuations represented management's best estimates, which involved inherent uncertainties and the application of significant levels of management judgment.

BLUE WATER VACCINES, INC.
Notes to Financial Statements

Note 3 — Summary of Significant Accounting Policies (cont.)

Risk-Free Interest Rate — The Company bases the risk-free interest rate on the implied yield available on U.S. Treasury securities with a remaining term commensurate with the estimated expected term.

Expected Dividend — The Company has never declared or paid any cash dividends on its common shares and does not plan to pay cash dividends in the foreseeable future, and, therefore, uses an expected dividend yield of zero in its valuation models.

The Company recognizes forfeitures of equity awards as they occur.

Fair value of common stock

In order to determine the fair value of shares of common stock of the Company when issuing stock options and computing their estimated stock-based compensation expense, its board of directors considered with input from third party valuations, among other things, contemporaneous valuations of the Company's common stock. Given the absence of a public trading market of the Company's capital stock to date, its board of directors has exercised reasonable judgment and considered a number of objective and subjective factors to determine the best estimate of the fair value of the Company common and preferred stock, including:

- the prices, rights, preferences and privileges of our preferred stock relative to our common stock;
- our business, financial condition and results of operations, including related industry trends affecting our operations;
- the likelihood of achieving a liquidity event, such as an initial public offering ("IPO"), or sale of our company, given prevailing market conditions;
- the lack of marketability of our common stock;
- the market performance of comparable publicly traded companies;
- U.S. and global economic and capital market conditions and outlook; and
- Common stock valuation methodology.

In estimating the fair market value of common stock of the Company, its board of directors first determined the equity value of its business using accepted valuation methods.

The Company engaged a third-party valuation specialist to conduct a valuation, which used its recent preferred stock financing as a starting point and determined the equity value of the company based on the Backsolve method using an Option Pricing Method (OPM) to calculate the implied value based on a market approach. The Company's equity value was allocated using OPM to estimate the fair market value of the Company's classes of equity.

Income Taxes

Income taxes are accounted for under the asset and liability method. Deferred tax assets and liabilities are recognized for future tax consequences attributable to differences between the financial statement carrying amounts of existing assets and liabilities and their respective tax bases and operating loss and tax credit carryforwards.

Deferred tax assets and liabilities are measured using enacted tax rates expected to apply to taxable income in the years in which those temporary differences are expected to be recovered or settled. The effect on deferred tax assets and liabilities of a change in tax rate is recognized in operations in the period that includes the enactment date. Deferred tax assets are reduced to estimated amounts expected to be realized by the use of a valuation allowance.

Under U.S. GAAP, the impact of an uncertain income tax position on the income tax return must be recognized at the largest amount that is more-likely-than-not to be sustained upon audit by the relevant taxing authority. An uncertain income tax position will not be recognized if it has less than a 50% likelihood of being sustained.

BLUE WATER VACCINES, INC.
Notes to Financial Statements

Note 3 — Summary of Significant Accounting Policies (cont.)

Additionally, U.S. GAAP provides guidance on derecognition, classification, interest and penalties, accounting for interim periods, disclosure and transition. The Company is currently not aware of any issues under review that could result in significant payments, accruals or material deviation from its position.

Comprehensive Income (Loss)

The Company is required to report all components of comprehensive income (loss), including net income (loss), in the accompanying financial statements in the period in which they are recognized. Comprehensive income (loss) is defined as the change in equity during a period from transactions and other events and circumstances from non-owner sources, including unrealized gains and losses on investments and foreign currency translation adjustments. Net loss and comprehensive loss were the same for all periods presented.

Net Loss Per Share

Basic loss per share is computed by dividing the net income or loss applicable to common shares by the weighted average number of common shares outstanding during the period. Diluted earnings per share is computed using the weighted average number of common shares and, if dilutive, potential common shares outstanding during the period. Potential common shares consist of the Company's preferred stock and options. Diluted loss per share excludes the shares issuable upon the conversion of preferred stock, common stock options from the calculation of net loss per share if their effect would be anti-dilutive.

The two-class method is used to determine earnings per share based on participation rights of participating securities in any undistributed earnings. Each preferred stock that includes rights to participate in distributed earnings is considered a participating security and the Company uses the two-class method to calculate net income available to the Company's common stockholders per share of common stock — basic and diluted.

The following were excluded from the computation of diluted shares outstanding due to the losses since inception, as they would have had an anti-dilutive impact on the Company's net loss:

	Six months ended June 30,		Years Ended December 31,	
	2021	**2020**	**2020**	**2019**
Options to purchase shares of common stock	195,160	229,604	195,160	57,404
Series Seed Preferred Stock	1,146,138	1,146,138	1,146,138	1,146,138
Total	**1,341,298**	**1,375,742**	**1,341,298**	**1,203,542**

New Accounting Pronouncements

On February 2016, the FASB issued Accounting Standards Update ("ASU") No. 2016-02, *Leases (Topic 842)*. Under the new guidance, lessees will be required to recognize all leases (with the exception of short-term leases) on the balance sheet as a lease liability, which is a lessee's obligation to make lease payments arising from a lease, measured on a discounted basis and a right-of-use asset, which is an asset that represents the lessee's right to use, or control the use of, a specified asset for the lease term. This guidance is effective for fiscal years beginning after December 15, 2020, and interim periods within fiscal years beginning after December 15, 2021, with early adoption permitted. On January 1, 2021, the Company adopted ASU No. 2016-02, and the adoption of this standard did not have an impact on the Company's financial statements as the Company is currently not subject to any lease agreements with terms in excess of 12 months.

In June 2018, the FASB issued ASU No. 2018-07, *Compensation — Stock Compensation (Topic 718): Improvements to Nonemployee Share-Based Payment Accounting* ("ASU 2018-07"). ASU 2018-07 simplifies several aspects of the accounting for nonemployee share-based payment transactions resulting from expanding the scope of

BLUE WATER VACCINES, INC.
Notes to Financial Statements

Note 3 — Summary of Significant Accounting Policies (cont.)

Topic 718, Compensation — Stock Compensation, to include share-based payment transactions for acquiring goods and services from non-employees. ASU 2018-07 is effective for public business entities for fiscal years beginning after December 15, 2018, including interim periods within that fiscal year. On January 1, 2019, the Company adopted ASU 2018-07, and the adoption did not have a material impact on its financial statements.

In December 2019, the FASB issued ASU No. 2019-12, *income Taxes (Topic 740): Simplifying the Accounting for Income Taxes* ("ASU 2019-12"), which is intended to simplify various aspects related to accounting for income taxes. ASU 2019-12 removes certain exceptions to the general principles in Topic 740 and also clarifies and amends existing guidance to improve consistent application. This guidance is effective for fiscal years, and interim periods within those fiscal years, beginning after December 15, 2020, with early adoption permitted. The Company adopted ASU 2019-12 on January 1, 2021. Adoption of the ASU did not impact the Company's financial position, results of operations or cash flows.

In August 2020, the FASB issued ASU No. 2020-06, *Debt — Debt with Conversion and Other Options (Subtopic 470-20) and Derivatives and Hedging — Contracts in Entity's Own Equity (Subtopic 815-40): Accounting for Convertible Instruments and Contracts in an Entity's Own Equity*, which simplifies accounting for convertible instruments by removing major separation models required under current GAAP. The ASU removes certain settlement conditions that are required for equity contracts to qualify for the derivative scope exception and it also simplifies the diluted earnings per share calculation in certain areas. This guidance is effective for fiscal years, and interim periods within those fiscal years, beginning after December 15, 2021, with early adoption permitted. The Company is currently evaluating the impact of this standard on its financial statements and related disclosures.

The Company's management does not believe that any other recently issued, but not yet effective, accounting standards if currently adopted would have a material effect on the accompanying financial statements.

Note 4 — Prepaid Expenses and Other Current Assets

Prepaid expense and other current assets consisted of the following as of June 30, 2021, December 31, 2020 and 2019:

	As of June 30, 2021	As of December 31, 2020	As of December 31, 2019
Prepaid expenses – research and development	$ 260,985	$ 233,532	$ —
Prepaid expenses – insurance	19,368	4,321	—
Prepaid expenses – consulting fees	70,000	35,000	—
Prepaid expenses – other	5,000	5,000	8
Total	**$ 355,353**	**$ 277,853**	**$ 8**

The prepaid expenses — consulting fees is prepaid to the Chief Executive Officer, pursuant to the consulting agreement as disclosed in Note 8.

Note 5 — Significant Agreements

Oxford University Innovation Limited

In December 2018, the Company entered into an option agreement Oxford University Innovation ("OUI"), which was a precursor to a license agreement (the "OUI Agreement"), dated July 16, 2019. Under the terms of the OUI Agreement, the Company holds an exclusive, worldwide license to certain specified patent rights and biological materials relating to the use of epitopes of limited variability and virus-like particle products and practice processes that are covered by the licensed patent rights and biological materials for the purpose of developing and commercializing a vaccine product candidate for influenza. The Company is obligated to use its best efforts to develop and market Licensed Products in accordance with its development plan, report to OUI on progress and achieve the following milestones and must pay OUI nonrefundable milestone fees as follows when it

BLUE WATER VACCINES, INC.
Notes to Financial Statements

Note 5 — Significant Agreements (cont.)

achieves them: initiation of first Phase I study; initiation of first Phase II study; initiation of first Phase III/pivotal registration studies; first submission of application for regulatory approval (BLA/NDA); marketing authorization in the United States; marketing authorization in any EU country; marketing authorization in Japan; first marketing authorization in any other country; first commercial sale in Japan; first commercial sale in any ROW country; first year that annual sales equal or exceed certain thresholds. The OUI Agreement will expire upon ten (10) years from the expiration of the last patent contained in the licensed patent rights, unless terminated earlier. None of the applications included in the OUI licensed patent rights have been issued as of December 31, 2020 and as of June 30, 2021. Either party may terminate the OUI Agreement for an uncured material breach. The Company may terminate the OUI Agreement for any reason at any time upon six months' written notice expiring after the third anniversary of the OUI Agreement. OUI may terminate immediately if the Company has a petition presented for its winding-up or passes a resolution for winding up other than for a bona fide amalgamation or reconstruction or compounds with its creditors or has a receiver or administrator appointed. OUI may also terminate if the Company opposes or challenges the validity of any of the patents or applications in the Licensed Technology; raises the claim that the know-how of the Licensed Technology is not necessary to develop and market Licensed Products; or in OUI's reasonable opinion, is taking inadequate or insufficient steps develop or market Licensed Products and does not take any further steps that OUI requests by written notice within a reasonable time.

For the years ended December 31, 2020 and 2019 and for the six month periods ended June, 30, 2021 and 2020, the Company did not incur any licensing fee payments for intellectual property licenses. See Note 7.

St. Jude Children's Hospital

The Company entered into a license agreement (the "St. Jude Agreement"), dated January 27, 2020, with St. Jude Children's Research Hospital ("St. Jude"). Under the terms of the St. Jude Agreement, the Company holds an exclusive, worldwide license to certain specified patent rights and biological materials relating to the use of live attenuated streptococcus pneumoniae and practice processes that are covered by the licensed patent rights and biological materials for the purpose of developing and commercializing a vaccine product candidate for streptococcus pneumoniae. The St. Jude Agreement will expire upon the expiration of the last valid claim contained in the licensed patent rights, unless terminated earlier. The Company is obligated to use commercially reasonable efforts to develop and commercialize the licensed product(s). The milestones include the following events: (i) complete IND enabling study; (ii) Initiate animal toxicology study; (iii) file IND; (iv) complete Phase I Clinical Trial; (v) commence Phase II Clinical Trial; (vi) commence Phase III Clinical Trial; and, (vii) regulatory approval, U.S. or foreign equivalent. If the Company fails to achieve the development milestones contained in the St. Jude Agreement, and if the Company and St. Jude fail to agree upon a mutually satisfactory revised timeline, St. Jude will have the right to terminate the St. Jude Agreement. Either party may terminate the St. Jude Agreement in the event the other party (a) files or has filed against it a petition under the Bankruptcy Act (among other things) or (b) fails to perform or otherwise breaches its obligations under the St. Jude Agreement, and has not cured such failure or breach within sixty (60) days. The Company may terminate for any reason on thirty (30) days written notice.

For the years ended December 31, 2019 and 2020 and for the six month periods ended June 30, 2021 and 2020, the Company recognized $0, $15,000 and $10,000, $15,000, respectively, for intellectual property licenses, which is recorded as research and development expenses. See Note 7.

Cincinnati Children's Hospital Medical Center

The Company entered into a license agreement (the "CHMC Agreement"), dated June 1, 2021, with Children's Hospital Medical Center, d/b/a Cincinnati Children's Hospital Medical Center ("CHMC"). Under the terms of the CHMC Agreement, the Company holds an exclusive, worldwide license (other than the excluded field of immunization against, and prevention, control, or reduction in the severity of gastroenteritis caused by rotavirus and norovirus in China and Hong Kong) to certain specified patent and biological materials relating to the use of norovirus nanoparticles and practice processes that are covered by the licensed patent rights and biological materials for the purpose of developing and commercializing CHMC patents and related technology directed to a virus-like particle

BLUE WATER VACCINES, INC.
Notes to Financial Statements

Note 5 — Significant Agreements (cont.)

vaccine platform that utilizes nanoparticle delivery technology that may have potential broad application to develop vaccines for multiple infectious diseases. The term of the CHMC Agreement begins on the effective date and extends on a jurisdiction by jurisdiction and product by product basis until the later of: (i) the last to expire licensed patent; (ii) ten (10) years after the first commercial sale; or, (iii) entrance onto the market of a biosimilar or interchangeable product. The Company is obligated to use commercially reasonable efforts to bring licensed products to market through diligent research and development, testing, manufacturing and commercialization and to use best efforts to make all necessary regulatory filings and obtain all necessary regulatory approvals, and achieve milestones relating to development and sales, and report to CHMC on progress. The Company will also be obligated to pay the agreed upon development milestone payments to CHMC. The Company may terminate the CHMC Agreement for convenience, at any time prior to first commercial sale of a product or process by providing one hundred and eighty (180) days' written notice to CHMC. It may also terminate for a CHMC uncured material breach. CHMC may terminate the CHMC Agreement for an uncured Company material breach or insolvency or bankruptcy. In the event the Company's material breach is for failure to meet any of the milestone payments, the Company is entitled to a nonexclusive license to continue developing indications that have already entered development at any stage or in which the Company has invested in developing. CHMC may also terminate the CHMC Agreement to the fullest extent permitted by law in the countries of the worldwide territory, in the event the Company or its affiliates challenge or induce others set up challenges to the validity or enforceability of any of the Licensed Patents and the Company will be obligated reimburse CHMC for its costs, including reasonable attorneys' fees.

For the six months ended June 30, 2021, the Company accrued licensing fee payments for intellectual property licenses, which is recorded as research and development expenses in aggregate of $377,104. See note 7.

Ology Bioservices, Inc. (which was later acquired by National Resilience, Inc.)

The Company entered into a Master Services Agreement ("Ology MSA"), dated July 19, 2019, with Ology, Inc. ("Ology") to provide service from time to time, including but not limited to technology transfer, process development, analytical method optimization, cGMP manufacture, regulatory affairs, and stability studies of biologic products. Pursuant to the Ology MSA, the Company and Ology shall enter into a Project Addendum for each project to be governed by the terms and conditions of the Ology MSA. The Company has entered into two Project Addendums as of June 30, 2021. The initial Project Addendum was executed October 18, 2019 and the Company was required to pay Ology an aggregate of approximately $4 million. Due to unforeseen delays associated with COVID-19, the Company and Resilience entered into a letter agreement dated January 9, 2020 to stop work on the project. The Company paid Ology $100,000 for services, of which $48,600 remains as prepaid expense as of December 31, 2020 and June 30, 2021. The second Project Addendum was executed May 21, 2021 and the Company is obligated to pay Ology an aggregate amount of approximately $2.8 million, plus reimbursement for materials and outsourced testing, which will be billed at cost plus 15%. No work was started as of June 30, 2021.

Note 6 — Stockholders' Equity

Authorized Capital

The Company is currently authorized to issue up to 2,300,000 shares of common stock, par value $0.00001 per share, and 1,150,000 shares of preferred stock, par value $0.00001 per share, of which 1,150,000 has been designated as Series Seed Preferred Stock.

Common Stock

As of June 30, 2021, December 31, 2020 and 2019, there were 800,000 shares of common stock issued and outstanding.

BLUE WATER VACCINES, INC.
Notes to Financial Statements

Note 6 — Stockholders' Equity (cont.)

The holders of the Company's common stock are entitled to one vote for each share held of record, and are entitled upon liquidation of the Company to share ratably in the net assets of the Company available for distribution after payment of all obligations of the Company and after provision has been made with respect to each class of stock, if any, having preference over the common stock, currently including the Company's preferred stock. The shares of common stock are not redeemable and have no preemptive or similar rights.

Preferred Stock

The Company has authorized 1,150,000 shares of preferred stock as Series Seed Preferred Stock ("Series Seed"), with an original issue price of $6.09 per share (the "Original Issue Price"). As of June 30, 2020, December 31, 2020 and 2019, there were 1,146,138 shares issued and outstanding.

Conversion

Each share of the Series Seed is convertible, at the option of the holder, at any time and from time to time, and without the payment of additional consideration by the holder, at a conversion price of $6.09 per share, subject to certain adjustments for stock splits, stock dividends, recapitalizations, and similar corporate transactions, into fully paid and non-assessable shares of the Company's common stock. Each Series Seed is automatically converted into common stock of the Company, at a conversion price of $6.09 per share, subject to adjustment, upon the closing a firmly underwritten public offering netting proceeds of at least $50 million with an offering price of at least three hundred percent (300%) of the Original Issue Price of the Series Seed.

Dividends

Holders of the Series Seed are entitled to receive cumulative dividends at a per share rate of 8% per annum, compounded annually, on the initial investment amount commencing on the date of issue. Dividends are payable only when, as, and if declared by the Board of Directors or upon a Liquidation Event, as described below. Dividends on Series Seed are in preference to any dividend on the Company's common stock.

Liquidation Preference

In the event of certain voluntary or involuntary acquisition or sale transactions or upon the liquidation, dissolution or winding up of the Company (each, a "Liquidation Event"), the holders of Series Seed shall be entitled to receive out of the proceeds or assets of the Company legally available for distribution to its stockholders (the "Proceeds"), prior and in preference to any distribution of the Proceeds of such Liquidation Event to the holders of common shares by reason of their ownership thereof, an amount per share equal to the greater of (i) the Original Issue Price per share, plus unpaid dividends at a per share rate of 8% per annum on the initial investment amount commencing on the date of issue and ending on the date of the Liquidation Event, or (ii) such amount per share as would have been payable had all shares of Series Seed been converted into common stock of the Company immediately prior to the Liquidation Event (the result referred to as the "Liquidation Preference Amount"). In the event that the Proceeds shall be insufficient to enable the distribution in full of the Liquidation Preference Amount to the holders of the Series Seed for all of the preferred shares held by them, all of the Proceeds shall be distributed among the holders of Series Seed on a pro rata basis. Upon completion of the distribution required to the holders of Series Seed, all of the remaining Proceeds available for distribution to stockholders shall be distributed among the holders of common shares pro rata based on the number of common shares held by each such holder.

Voting

On any matter presented to the stockholders' of the Company for their action or consideration at any meeting of stockholders' of the Company (or by written consent of stockholders in lieu of meeting), each holder of outstanding shares of Series Seed will be entitled to cast the number of votes equal to the number of whole shares

BLUE WATER VACCINES, INC.
Notes to Financial Statements

Note 6 — Stockholders' Equity (cont.)

of common stock into which the shares of Series Seed held by such holder are convertible as of the record date for determining stockholders' entitled to vote on such matter. Holders of Series Seed will vote together with the holders of common stock as a single class. Holders of Series Seed are entitled to nominate two out of five of the Company's directors.

Stock Transactions

On July 1, 2019, the Company entered into a Series Seed Preferred Stock Purchase Agreement ("Purchase Agreement") with five qualified investors. The investors agreed to purchase and the Company agreed to sell and issue to investors a total of 1,146,138 shares of Series Seed Preferred Stock, $0.00001 par value per share, at a purchase price of $6.09 per share. On July 1, 2019, the Company received approximately $6.9 million (net of offering costs of approximately $45,000) in cash from investors in exchange for the issuance of 1,146,138 shares of Series Seed Preferred Stock.

2019 Equity Incentive Plan

The Company's 2019 Equity Incentive Plan (the "2019 Plan") was adopted by its board of directors and by its stockholders on July 1, 2019. The Company has reserved 350,000 shares of common stock for issuance pursuant to the 2019 Plan.

Stock Options

On December 19, 2019, the Company granted options to purchase up to 57,404 shares of the Company's common stock to an employee pursuant to the 2019 Plan. The aggregate grant date fair value of these options was approximately $0.2 million. The employee resigned from the Company effective August 31, 2020 and was retained as a consultant starting September 1, 2020. Pursuant to the amended stock option agreement, the employee forfeited 34,444 shares of options originally granted. The remaining shares of options remain original terms and conditions.

During the year ended December 31, 2020, the Company granted options to purchase up to 172,200 shares of the Company's common stock to its board members and employees pursuant to the 2019 Plan. The aggregate grant date fair value of these options was approximately $0.5 million.

The fair value of options granted in 2020 and 2019 was estimated using the following assumptions:

	For the Years Ended December 31,	
	2020	**2019**
Exercise price	$0.05	$0.05
Term (years)	5.03 – 6.98	5.50 – 7.02
Expected stock price volatility	112.2% – 115.2%	113.0% – 113.5%
Risk-free rate of interest	0.37% – 1.76%	1.73% – 1.86%

BLUE WATER VACCINES, INC.
Notes to Financial Statements

Note 6 — Stockholders' Equity (cont.)

A summary of stock option activity for the six months ended June 30, 2021 and years ended December 31, 2020 and 2019 is presented below:

	Number of Shares	Weighted Average Exercise Price	Total Intrinsic Value	Weighted Average Remaining Contractual Life (in years)
Outstanding as of December 31, 2018	—	$ —	$ —	—
Granted	57,404	0.05	156,713	10.0
Outstanding as of December 31, 2019	57,404	$ 0.05	$ 156,713	10.0
Granted	172,200	0.05	470,106	9.1
Forfeited	(34,444)	—	—	—
Outstanding as of December 31, 2020	195,160	$ 0.05	$ 532,787	9.1
Outstanding as of June 30, 2021	195,160	$ 0.05	$ 532,787	8.6
Options vested and exercisable as of June 30, 2021	85,134	$ 0.05	$ 232,416	8.6

Stock-based compensation

Stock-based compensation expense for the six months ended June 30, 2021 and 2020, and for the years ended December 31, 2020 and 2019 were as follows:

	For the six months ended June 30,		For the Years Ended December 31,	
	2021	2020	2020	2019
General and administrative	$ 23,876	$ 62,950	$ 89,555	$ 1,633
Research and development	52,769	172,860	245,282	1,633
Total	**$ 76,645**	**$ 235,810**	**$ 334,837**	**$ 3,266**

As of June 30, 2021, future stock-based compensation expense relating to outstanding stock options is approximately $0.1 million and will be recorded through December 2023.

Note 7 — Commitments and Contingencies

Office lease

The Company leased office space for approximately $5,500 a month from a related party. The Company paid a $15,000 rental deposit and rent expense for the six months ended June 30, 2021 and 2020 and for the years ended December 31, 2020 and 2019 was approximately $28,000, $33,000, $66,000 and $66,000, respectively. The Company terminated the related party lease in May 2021 and entered into a new lease with an unrelated party in April 2021. The Company is not a party to a lease with a term in excess of 12 months and has a month-to-month lease as of June 30, 2021.

Litigation

From time to time, the Company may be subject to various legal proceedings and claims that arise in the ordinary course of its business activities. The Company is not a party to any material legal proceedings and is not aware of any pending or threatened claims.

BLUE WATER VACCINES, INC.
Notes to Financial Statements

Note 7 — Commitments and Contingencies (cont.)

Significant agreements

Oxford University Innovation Limited

Pursuant to the OUI Agreement, as disclosed in Note 5, the Company is obligated to pay a 6% royalty on all net sales of licensed products, as defined in the OUI Agreement, as well as on any sums received by the Company from any sublicensee (including all up-front, milestone and other one-off payments received by the Company from any sub-licenses or other contracts granted by the Company with respect to the licensed technology). In addition, the Company is required to pay OUI milestone payments of up to an aggregate of $51 million upon the achievement of specified development milestones, of approximately $2.25 million, regulatory milestones, of approximately $9.5 million and commercial milestones, of approximately $39.5 million.

Oxford University Research Agreement

Pursuant to the terms of the OUI Agreement, as disclosed in Note 5, the Company entered into a sponsored research agreement dated December 18, 2019 with Oxford University for research related to the OUI Agreement for a period of three years for a total of £420,000. The Company prepaid the full amount to Oxford of $554,802 for the services in January 2020, of which approximately $0.3 million and $0.4 million remains as prepaid expense as of June 30, 2021 and December 31, 2020, respectively.

St. Jude Children's Hospital

Pursuant to the St. Jude Agreement, as disclosed in Note 5, the Company is obligated to make 4% royalty payments for each licensed product(s) sold by the Company or its affiliates, based on the net sales for the duration of the St. Jude Agreement and also pay 15% of consideration received for any sublicenses. The Company is required to pay an annual maintenance fee of $10,000 beginning on the first anniversary of the Effective Date (which is waived if all of the developmental milestones scheduled for completion before such annual fee is due have been achieved). In addition, the Company is required to pay St. Jude milestone payments of up to an aggregate of $1 million upon the achievement of specified development milestones, of approximately $ 0.2 million, regulatory milestones, of approximately $0.3 million and commercial milestones, of approximately $0.5 million.

St. Jude Children's Sponsored Research Agreement

In addition to the St. Jude Agreement, the Company also entered into a sponsored research agreement dated May 3, 2021 with St. Jude for research related to the St. Jude Agreement. Pursuant to this research agreement, the Company is obligated to pay St. Jude an aggregate amount of $73,073 in two parts, Phase I for $57,624 and Phase II for $15,449. As of June 30, 2021, the Company accrued the Phase I payment of $57,624 which is recorded as research and development expenses.

Cincinnati Children's Hospital Medical Center

Pursuant to the CHMC Agreement, as disclosed in Note 5, the Company is obligated to pay CHMC a single-digit royalty on net sales, being 5%, 4% or 2% depending on the product, under the agreement and to pay up to a 25% royalty on any royalties paid to the Company by any sublicensee. In addition, the Company is required to pay CHMC and aggregate of up to $59.75 million upon the achievement of specified development milestones, of approximately $0.5 million, regulatory milestones, of approximately $1.25 million and commercial milestones, of approximately $58 million.

Ology Bioservices, Inc. (which was later acquired by National Resilience, Inc.)

Pursuant to the Ology MSA and the second Project Addendum, as disclosed in Note 5, the Company is obligated to pay Ology an aggregate amount of approximately $2.8 million, plus reimbursement for materials and outsourced testing which will be billed at cost plus 15%. No work was started as of June 30, 2021.

BLUE WATER VACCINES, INC.
Notes to Financial Statements

Note 7 — Commitments and Contingencies (cont.)

Indemnification

In the normal course of business, the Company enters into contracts and agreements that contain a variety of representations and warranties and provide for general indemnifications. The Company's exposure under these agreements is unknown because it involves claims that may be made against the Company in the future but have not yet been made. To date, the Company has not paid any claims or been required to defend any action related to its indemnification obligations. However, the Company may incur charges in the future as a result of these indemnification obligations.

Risks and Uncertainties — COVID-19

Management continues to evaluate the impact of the COVID-19 pandemic on the industry and has concluded that while it is reasonably possible that the virus could have a negative effect on the Company's financial position, results of its operations and/or search for drug candidates, the specific impact is not readily determinable as of the date of these financial statements. The financial statements do not include any adjustments that might result from the outcome of this uncertainty.

Note 8 — Related Party Transactions

The Company has engaged the Chief Executive Officer, who is also the Board Chairman and sole common stockholder, of the Company pursuant to a consulting agreement commencing October 22, 2018, which calls for the Company to pay for consulting services performed on a monthly basis. For the six months ended June 30, 2021 and years ended December 31, 2020 and 2019, the Company incurred approximately $0.2 million, $0.4 million and $0.4 million, respectively in fees under the consulting agreement, which are recognized in general and administrative expenses in the statements of operations.

The Company also leased office space from a related party, through common ownership, and had a rental deposit of $15,000 on the balance sheets as of December 31, 2020 and 2019. The lease is further described in Note 7 of these financial statements.

As of June 30, 2021, December 31, 2020 and 2019, the Company has a receivable from the related party of approximately $22,000, $10,000 and $8,000, respectively, as presented on the balance sheets. The receivable from related party consists of utility expense paid, rental deposit due subsequent to cancellation of the lease, and overpaid rent expenses.

One of the Company's directors serves on the Advisory Board for the Cincinnati Children's Hospital Medical Center Innovation Fund, which is affiliated with CHMC. The Company has an exclusive license agreement with CHMC as disclosed in Note 5.

Note 9 — Income Taxes

At December 31, 2020, the Company had a net operating loss ("NOL") carryforward for Federal and state income tax purposes totaling approximately $2.1 million available to reduce future taxable income, all of which are carried forward indefinitely for federal tax purposes under the Tax Cuts and Jobs Act. The Coronavirus Aid, Relief, and Economic Security Act ("CARES Act") signed in to law on March 27, 2020, provided that NOLs generated in a taxable year beginning in 2018, 2019, or 2020, may now be carried back five years and forward indefinitely. In addition, the limitation of NOL utilization up to 80% of taxable income limitation is temporarily removed, allowing NOLs to fully offset taxable income. Some of the state net operating losses follow the Federal Tax Cuts and Jobs Act and are carried over indefinitely, and others have various expiration dates.

The NOL carry forward is subject to review and possible adjustment by the Internal Revenue Service and state tax authorities. Under the Internal Revenue Code ("IRC") Sections 382 and 383, annual use of the Company's net operating loss carryforwards to offset taxable income may be limited based on cumulative changes in ownership. The Company has not completed an analysis to determine whether any such limitations have been triggered as

BLUE WATER VACCINES, INC.
Notes to Financial Statements

Note 9 — Income Taxes (cont.)

of December 31, 2020. The amount of the annual limitation, if any, will be determined based on the value of the Company immediately prior to the ownership change. Subsequent ownership changes may further affect the limitation in future years.

The Company has evaluated the positive and negative evidence bearing upon the realizability of its deferred tax assets. Based on the Company's history of operating losses since inception, the Company has concluded that it is more likely than not that the benefit of its deferred tax assets will not be realized. Accordingly, the Company has provided a full valuation allowance for deferred tax assets as of December 31, 2020 and 2019.

The tax effects of the temporary differences and carryforwards that give rise to deferred tax assets consist of the following:

	As of December 31,	
	2020	**2019**
Deferred tax assets:		
Net-operating loss carryforward	$ 554,813	$ 235,363
Stock-based compensation	91,035	880
License agreement	20,848	—
Charitable contributions	11,247	477
Other accrued expenses	—	15,451
Total deferred tax assets	677,943	252,171
Valuation allowance	(677,943)	(252,171)
Deferred tax asset, net of allowance	$ —	$ —

A reconciliation of the statutory income tax rates and the Company's effective tax rate is as follows:

	For the year ended December 31,	
	2020	**2019**
Statutory Federal income tax rate	(21.0)%	(21.0)%
State and local taxes, net of Federal tax benefit	(5.9)%	(5.9)%
Meals and entertainment	0.3%	0.1%
Change in Valuation Allowance	26.6%	26.8%
Income Taxes Provision (Benefit)	0.0%	0.0%

The Company's major tax jurisdictions are the United States and Connecticut and the Company does not have any pending tax audits.

2,222,222 Shares

Common Stock

PROSPECTUS

, 2021

Sole Book-Running Manager

Maxim Group LLC

Through and including , 2021 (25 days after the date of this prospectus), all dealers that buy, sell or trade shares of our common stock, whether or not participating in this offering, may be required to deliver a prospectus. This delivery requirement is in addition to the obligation of dealers to deliver a prospectus when acting as underwriters and with respect to their unsold allotments or subscriptions.

PART II

INFORMATION NOT REQUIRED IN PROSPECTUS

Item 13. 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 and to FINRA.

		Amount to be paid
SEC registration fee	$	2,254.70
FINRA filing fee	$	4,148.38
Nasdaq initial listing fee	$	*
Blue sky qualification fees and expenses	$	*
Transfer agent and registrar fees	$	*
Accounting fees and expenses	$	*
Legal fees and expenses	$	*
Printing and engraving expenses	$	*
Miscellaneous	$	*
Total	$	*

* To be completed by amendment.

Item 14. Indemnification of Directors and Officers

As permitted by Section 102 of the Delaware General Corporation Law, we will adopt provisions in our Amended and Restated Certificate of Incorporation and our Amended and Restated Bylaws that 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 will 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 of 1933, as amended, or 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 form of underwriting agreement for this initial public offering provides for indemnification by the underwriters of us and our officers and directors who sign this registration statement for specified liabilities, including matters arising under the Securities Act.

Item 15. Recent Sales of Unregistered Securities

Since October 2018 (our date of inception), we have made the following sales of unregistered securities:

(1) We granted to certain employees, consultants and directors options to purchase an aggregate of 195,160 shares (net of certain forfeitures of grants) of our common stock at an exercise price of $0.05 per share.

(2) We issued an aggregate of 1,146,138 shares of Series Seed Preferred Stock (convertible (as of September 30, 2021) into 1,372,371 shares of common stock) in July 2019 to 5 accredited investors at a price of $6.09 per share for an aggregate purchase price of $6,979,980.

The offers, sales and issuances of the securities described in paragraph (1) were deemed to be exempt from registration under Rule 701 promulgated under the Securities Act as transactions under compensatory benefit plans and contracts relating to compensation, or under Section 4(a)(2) of the Securities Act as a transaction by an issuer not involving a public offering. The recipients of such securities were our directors, employees or bona fide consultants and received the securities under our equity incentive plans. Appropriate legends were affixed to the securities issued in these transactions. Each of the recipients of securities in these transactions had adequate access, through employment, business or other relationships, to information about us.

The offers, sales and issuances of the securities described in paragraph (2) were deemed to be exempt under Section 4(a)(2) of the Securities Act or Rule 506 of Regulation D under the Securities Act as a transaction by an issuer not involving a public offering. The recipients of securities in each of these transactions acquired the securities for investment only and not with a view to or for sale in connection with any distribution thereof and appropriate legends were affixed to the securities issued in these transactions. Each of the recipients of securities in these transactions was an accredited investor within the meaning of Rule 501 of Regulation D under the Securities Act and had adequate access, through employment, business or other relationships, to information about us. No underwriters were involved in these transactions.

Item 16. Exhibits and Financial Statement Schedules

Exhibit No.	Description
1.1	Form of Underwriting Agreement.**
3.1	Certificate of Incorporation.***
3.2	Amended and Restated Certificate of Incorporation.***
3.3	Amended and Restated Certificate of Incorporation, effective upon the consummation of the offering.*
3.4	Bylaws.***
3.5	Amended and Restated Bylaws.***
4.1	Specimen Common Stock Certificate.*
4.2	Form of Representative's Warrant (included in Exhibit 1.1)**
5.1	Opinion of Ellenoff Grossman & Schole LLP.**
10.1	2019 Equity Incentive Plan.***
10.2	2021 Equity Incentive Plan.***
10.3	2019 Equity Incentive Plan Form of Stock Option Grant Agreement.***
10.4	2021 Equity Incentive Plan Form of Incentive Stock Option Agreement (Employee).***
10.5	2021 Equity Incentive Plan Form of Nonstatuory Stock Option Agreeement (Consultant).***
10.6	2021 Equity Incentive Plan Form of Nonstatuory Stock Option Agreeement (Non-Employee Director).***
10.7	2021 Equity Incentive Plan Form of Nonstatuory Stock Option Agreeement (Employee).***
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.*
10.9#	License Agreement between the Registrant and Oxford University Innovation Limited, effective as of July 16, 2019.*
10.10#	Exclusive License Agreement between the Registrant and St. Jude Children's Research Hospital, Inc., effective as of January 27, 2020.*
10.11	Lease Agreement, dated as of April 29, 2021, between the Registrant and Regus Management Group, LLC.***
10.12	Master Services Agreement between the Registrant and Ology Bioservices, Inc., effective as of July 19, 2019.***
10.13	Project Addendum 1 to Master Services Agreement between the Registrant and Ology Bioservices, Inc., effective as of October 9, 2019.***
10.14	Letter Agreement between the Registrant and Ology Bioservices, Inc., dated as of January 9, 2020.***
10.15	Project Addendum II to Master Services Agreement between the Registrant and Ology Bioservices, Inc., effective as of May 21, 2021.***
10.16	Form of Employment Agreement with Joseph Hernandez.***
10.17	Form of Employment Agreement with Erin Henderson.***
10.18	Form of Indemnification Agreement for Directors and Officers.***
14	Code of Ethics.**
23.1	Consent of Mayer Hoffman McCann P.C.*
23.2	Consent of Ellenoff Grossman & Schole LLP (included in Exhibit 5.1).**
24.1	Power of Attorney.***
99.1	Form of Audit Committee Charter.**
99.2	Form of Compensation Committee Charter.**
99.3	Form of Nominating and Corporate Governance Committee Charter.**
99.4	Consent of James Sapirstein.***

* Filed herewith.
** To be filed by amendment.
*** Filed as part of this registration statement on Form S-1 (Registration No. 333-260137) on October 8, 2021.
# Portions of this exhibit (indicated by asterisks) have been omitted as such information is (i) not material and (ii) would likely cause competitive harm to the Registrant if publicly disclosed.

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 Commission pursuant to Rule 424(b) if, in the aggregate, the changes in volume and price represent no more than 20% change in the maximum aggregate offering price set forth in the "Calculation of Registration Fee" table in the effective registration statement.

   (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. For the purposes of determining any liability under the Securities Act of 1933, each post-effective amendment that contains a form of prospectus 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. For the purpose of determining liability under the Securities Act of 1933 to any purchaser:

   (i) If the registrant is relying on Rule 430B:

      (a) Each prospectus filed by the registrant pursuant to Rule 424(b)(3) shall be deemed to be part of the registration statement as of the date the filed prospectus was deemed part of and included in the registration statement; and

      (b) Each prospectus required to be filed pursuant to Rule 424(b)(2), (b)(5), or (b)(7) as part of a registration statement in reliance on Rule 430B relating to an offering made pursuant to Rule 415(a)(1)(i), (vii), or (x) for the purpose of providing the information required by section 10(a) of the Securities Act of 1933 shall be deemed to be part of and included in the registration statement as of the earlier of the date such form of prospectus is first used after effectiveness or the date of the first contract of sale of securities in the offering described in the prospectus. As provided in Rule 430B, for liability purposes of the issuer and any person that is at that date an underwriter, such date shall be deemed to be a new effective date of the registration statement relating to the securities in the registration statement to which that prospectus relates, and the offering of such securities at that time shall be deemed to be the initial bona fide offering thereof. 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 effective date, 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 effective date; or

(ii) If the registrant is subject to Rule 430C, 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, 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. For the purposes of determining liability under the Securities Act of 1933 to any purchaser in the initial distributions 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.

6. The undersigned registrant hereby undertakes to provide to the underwriter at the closing specified in the underwriting agreements certificates in such denominations and registered in such names as required by the underwriter to permit prompt delivery to each purchaser.

7. The undersigned registrant hereby undertakes that:

(i) For purposes of determining any liability under the Securities Act of 1933, the information omitted from the form of prospectus filed as part of this registration statement in reliance upon Rule 430A and contained in a form of prospectus filed by the registrant pursuant to Rule 424(b) (1) or (4) or 497(h) under the Securities Act shall be deemed to be part of this registration statement as of the time it was declared effective.

(ii) For the purpose of determining any liability under the Securities Act of 1933, each post-effective amendment that contains a form of prospectus 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.

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

SIGNATURES

Pursuant to the requirements of the Securities Act of 1933, the registrant has duly caused this registration statement to be signed on its behalf by the undersigned, thereunto duly authorized, in the City of Cincinnati, State of Ohio, on the 4th day of November, 2021.

Blue Water Vaccines, Inc.

/s/ Joseph Hernandez
Name: Joseph Hernandez
Title: Chief Executive Officer
(Principal Executive Officer)

Pursuant to the requirements of the Securities Act of 1933, this registration statement has been signed by the following persons in the capacities and on the dates indicated.

Name	Position	Date
/s/ Joseph Hernandez Joseph Hernandez	Chief Executive Officer (Principal Executive Officer)	November 4, 2021
* Jon Garfield	Interim Chief Financial Officer (Principal Financial Officer)	November 4, 2021
* Kimberly Murphy	Director	November 4, 2021
* John Rice, Ph.D.	Director	November 4, 2021
/s/* Allan L. Shaw	Director	November 4, 2021
*By /s/ Joseph Hernandez Joseph Hernandez *Attorney-in-Fact*	Director	November 4, 2021

Exhibit 3.3

AMENDED AND RESTATED
CERTIFICATE OF INCORPORATION
OF
BLUE WATER VACCINES, INC.

Blue Water Vaccines, Inc. (the "Corporation"), a corporation organized and existing under and by virtue of the provisions of the General Corporation Law of the State of Delaware (the "General Corporation Law"), hereby certifies that:

FIRST. The name under which the Corporation was originally incorporated is Blue Water Vaccines, Inc.

SECOND. The Certificate of Incorporation of the Corporation was originally filed with the Secretary of State of Delaware on October 26, 2018. A first Amended and Restated Certificate of Incorporation was filed on July 1, 2019. The Certificate of Incorporation of the Corporation as heretofore amended is hereby amended and restated pursuant to Sections 228, 242 and 245 of the General Corporation Law. All amendments to the Certificate of Incorporation reflected herein (this "Restated Certificate") have been duly adopted by the Board of Directors and stockholders of the Corporation in accordance with the provisions of such Sections. As required by Section 228 of the General Corporation Law, the Corporation has given written notice of the amendments reflected herein to all stockholders who did not consent in writing to these amendments.

THIRD. The Certificate of Incorporation of the Corporation shall be amended and restated to read in full as follows:

ARTICLE I.

The name of this corporation is Blue Water Vaccines, Inc.

ARTICLE II.

The address of the Corporation's registered office in the State of Delaware is VCorp Services, LLC, 1013 Centre Road, Suite 403-B, in the City of Wilmington, County of New Castle, Delaware 19805. The name of its registered agent at such address is The VCorp Services, LLC.

ARTICLE III.

The purpose of the Corporation is to engage in any lawful act or activity for which a corporation may be organized under the General Corporation Law of the State of Delaware.

ARTICLE IV.

A. Classes of Stock and Authorized Shares. The Corporation is authorized to issue two classes of stock to be designated, respectively, Common Stock, par value $0.0001 per share (the "Common Stock"), and Preferred Stock, par value $0.0001 per share (the "Preferred Stock"). The total number of shares which the Corporation is authorized to issue is 260,000,000 shares, of which 250,000,000 shares shall be Common Stock, and 10,000,000 shares shall be Preferred Stock.

B. Rights, Powers, Preferences and Restrictions of Preferred Stock. The Board of Directors of the corporation is hereby expressly authorized, by resolution or resolutions thereof and the filing of a certificate pursuant to the applicable law of the State of Delaware (hereinafter referred to as a "Preferred Stock Designation"), to provide, out of the unissued shares of Preferred Stock, for one or more series of Preferred Stock and, with respect to each such series, to fix the number of shares constituting such series and the designation of such series, the voting powers, if any, of the shares of such series, and the preferences and relative, participating, optional or other special rights, if any, and any qualifications, limitations or restrictions thereof, of the shares of such series. The powers, preferences and relative, participating, optional and other special rights of each series of Preferred Stock, and the qualifications, limitations or restrictions thereof, if any, may differ from those of any and all other series at any time outstanding. Subject to Section A of this Article IV and any Preferred Stock Designation, the Board is also expressly authorized to increase or decrease the number of shares of any series of Preferred Stock subsequent to the issuance of shares of that series, but not below the number of shares of such series then outstanding. Unless otherwise expressly provided in the certificate of designations in respect of any series of Preferred Stock, in case the number of shares of such series shall be decreased in accordance with the foregoing sentence, the shares constituting such decrease shall resume the status that they had prior to the adoption of the resolution originally fixing the number of shares of such series.

C. Rights of Common Stock. The relative powers, rights, qualifications, limitations and restrictions granted to or imposed on the shares of the Common Stock are as follows:

1. General. The voting powers and dividend and liquidation rights and preferences, if any, of the holders of the Common Stock are subject to and qualified by the rights of the holders of the Preferred Stock of any series as may be designated by the Board of Directors upon any issuance of the Preferred Stock of any series.

2. Voting Rights. Except as may be otherwise provided by this Restated Certificate, a Preferred Stock Designation or by applicable law, the holders of the Common Stock shall be entitled to one vote for each share upon each matter presented to the stockholders of the Corporation; *provided, however*, that, except as otherwise required by law, holders of Common Stock shall not be entitled to vote on any amendment to this Restated Certificate or a Preferred Stock Designation that relates solely to the terms of one or more outstanding series of Preferred Stock if the holders of such affected series are entitled, either separately or together as a class with the holders of one or more other such series, to vote thereon pursuant to this Restated Certificate, a Preferred Stock Designation or the General Corporation Law. There shall be no cumulative voting. The number of authorized shares of Common Stock may be increased or decreased (but not below the number of shares thereof then outstanding) by the affirmative vote of the holders of a majority of the voting power of the capital stock of the Corporation entitled to vote thereon, voting as a single class, irrespective of the provisions of Section 242(b)(2) of the General Corporation Law.

3. Dividends. Dividends may be declared and paid on the Common Stock from funds lawfully available therefor as and when determined by the Board of Directors and subject to any preferential dividend or other rights of any then outstanding Preferred Stock and to the requirements of applicable law.

4. Liquidation. Upon the dissolution or liquidation of the Corporation, whether voluntary or involuntary, holders of Common Stock will be entitled to receive all assets of the Corporation legally available for distribution to its stockholders, subject to any preferential or other rights of any then outstanding Preferred Stock.

ARTICLE V.

In furtherance and not in limitation of the powers conferred upon it by the General Corporation Law, and subject to the terms of any series of Preferred Stock, the Board of Directors is expressly authorized and empowered to adopt, amend or repeal the Bylaws of the Corporation. The stockholders may not adopt, amend, alter or repeal the Bylaws of the Corporation, or adopt any provision inconsistent therewith, unless such action is approved, in addition to any other vote required by this Restated Certificate, by the affirmative vote of the holders of at least 66 2/3% in voting power of the outstanding shares of capital stock of the Corporation entitled to vote thereon. Notwithstanding any other provisions of law, this Restated Certificate or the Bylaws of the Corporation, and notwithstanding the fact that a lesser percentage may be specified by law, the affirmative vote of the holders of at least 66 2/3% in voting power of the outstanding shares of capital stock of the Corporation entitled to vote thereon shall be required to amend or repeal, or to adopt any provision inconsistent with, this Article V.

ARTICLE VI.

A. Authority of Board. The business and affairs of the Corporation shall be managed by or under the direction of the Board of Directors. In addition to the powers and authority expressly conferred by statute or by this Restated Certificate or the Bylaws of the Corporation, the Board of Directors is hereby empowered to exercise all such powers and do all such acts and things as may be exercised or done by the Corporation.

B. Board Size. Subject to the rights of the holders of any series of Preferred Stock to elect additional directors pursuant to any Preferred Stock Designation, the total number of authorized directors constituting the Board of Directors (the "Whole Board") shall be fixed from time to time exclusively by the Board of Directors pursuant to a resolution adopted by a majority of the Whole Board.

C. Classified Board Structure. From and after the Effective Time (defined below), the directors, other than any who may be elected by the holders of any series of Preferred Stock pursuant to any Preferred Stock Designation, shall be divided into three (3) classes hereby designated Class I, Class II and Class III. The Board of Directors may assign members of the Board of Directors already in office to such classes at the time such classification becomes effective. The term of office of the initial Class I directors shall expire at the first annual meeting of the stockholders to be held following the effectiveness of this Restated Certificate (the "Effective Time"), the term of office of the initial Class II directors shall expire at the second annual meeting of the stockholders following the Effective Time, and the term of office of the initial Class III directors shall expire at the third annual meeting of the stockholders following the Effective Time. At each annual meeting of stockholders, commencing with the first annual meeting of stockholders following the Effective Time, each of the successors elected to replace the directors of a Class whose term shall have expired at such annual meeting shall be elected to hold office until the third annual meeting next succeeding his or her election and until his or her respective successor shall have been duly elected and qualified or until his or her earlier death, resignation, or removal.

D. Removal; Vacancies. Any director may be removed from office by the stockholders of the Corporation only for cause by the affirmative vote of the holders of at least 66 2/3% of the outstanding voting power of the stockholders entitled to vote thereon. Vacancies occurring on the Board of Directors for any reason and newly created directorships resulting from an increase in the authorized number of directors may be filled exclusively pursuant to a resolution adopted by the Board of Directors and not by the stockholders. A person elected to fill a vacancy or newly created directorship shall hold office until the next election of the class for which such director shall have been chosen and until his or her successor shall be duly elected and qualified.

ARTICLE VII.

A. No Cumulative Voting. No stockholder will be permitted to cumulate votes in any election of directors. The election of directors need not be by written ballot unless the Bylaws of the Corporation shall so provide.

B. Special Meetings. Special meetings of the stockholders may be called only by (i) the Board of Directors pursuant to a resolution adopted by a majority of the Whole Board; (ii) the chairman of the Board of Directors; or (iii) the chief executive officer or president of the Corporation.

C. No Stockholder Action by Written Consent. Subject to the rights of the holders of any series of Preferred Stock, any action required or permitted to be taken by the stockholders of the Corporation must be effected at a duly called annual or special meeting of stockholders of the Corporation and may not be effected by any consent in writing by such stockholders.

ARTICLE VIII.

A Forum Selection. Subject to the last sentence in this Article VIII(A), and unless the Corporation consents in writing to the selection of an alternative forum, to the fullest extent permitted by the applicable law, the Court of Chancery of the State of Delaware shall be the sole and exclusive forum for any stockholder (including a beneficial owner) to bring (i) any derivative action or proceeding brought on behalf of the Corporation, (ii) any action asserting a claim of breach of a fiduciary duty owed by any director, officer or other employee of the Corporation to the Corporation or the Corporation's stockholders, (iii) any action asserting a claim against the Corporation, its directors, officers or employees arising pursuant to any provision of the DGCL or this Restated Certificate or the By-Laws, or (iv) any action asserting a claim against the Corporation, its directors, officers or employees governed by the internal affairs doctrine and, if brought outside of Delaware, the stockholder bringing the suit will be deemed to have consented to service of process on such stockholder's counsel 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. Notwithstanding the foregoing, (i) the provisions of this Article VIII(A) will not apply to suits brought to enforce any liability or duty created by the Exchange Act or any other claim for which the federal courts have exclusive jurisdiction and (ii) unless the Corporation consents 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 of 1933, as amended, or the rules and regulations promulgated thereunder.

B. Consent to Jurisdiction. If any action the subject matter of which is within the scope of Article VIII(A) immediately above is filed in a court other than a court located within the State of Delaware (a "***Foreign Action***") in the name of any stockholder, such stockholder shall be deemed to have consented to (i) the personal jurisdiction of the state and federal courts located within the State of Delaware in connection with any action brought in any such court to enforce Article VIII(A) immediately above (an "***FSC Enforcement Action***") and (ii) having service of process made upon such stockholder in any such FSC Enforcement Action by service upon such stockholder's counsel in the Foreign Action as agent for such stockholder.

C. Severability. If any provision or provisions of this *Article VIII* shall be held to be invalid, illegal or unenforceable as applied to any person or entity or circumstance for any reason whatsoever, then, to the fullest extent permitted by law, the validity, legality and enforceability of such provisions in any other circumstance and of the remaining provisions of this *Article VIII* (including, without limitation, each portion of any sentence of this *Article VIII* containing any such provision held to be invalid, illegal or unenforceable that is not itself held to be invalid, illegal or unenforceable) and the application of such provision to other persons or entities and circumstances shall not in any way be affected or impaired thereby.

D. Deemed Notice. Any person or entity purchasing or otherwise acquiring or holding any interest in any security of the Corporation shall be deemed to have notice of and consented to this Article VIII.

ARTICLE IX.

A. The Corporation shall indemnify (and advance expenses to) its officers and directors to the full extent permitted by the General Corporation Law, as amended from time to time.

B. To the fullest extent permitted by law, no director of the Corporation shall be personally liable to the Corporation or its stockholders for monetary damages for any breach of fiduciary duty as a director, notwithstanding any provision of law imposing such liability.

C. No amendment to or repeal of this provision, nor the adoption of any provision of the Restated Certificate inconsistent with this Article IX, shall apply to or have any effect on (1) the liability or alleged liability of any director of the Corporation or the (2) indemnification and advancement rights of any director or officer, in each case, for or with respect to any acts or omissions of such director or officer occurring prior to such amendment or repeal. If the General Corporation Law is amended to permit further elimination or limitation of the personal liability of directors or to permit greater indemnification or advancement rights of directors and officers, then the directors and officers of the Corporation shall be protected from liability (whether through exculpation, indemnification or advancement rights) the fullest extent permitted by the General Corporation Law as so amended.

ARTICLE X.

The Corporation reserves the right to amend, alter, change or repeal any provision contained in this Restated Certificate, in the manner now or hereafter prescribed by statute, and all rights conferred upon stockholders herein are granted subject to this reservation. Notwithstanding any other provision of this Restated Certificate or applicable law and in addition to any affirmative vote of the holders of any particular class of stock of the Corporation required by applicable law or by a Preferred Stock Designation or this Restated Certificate, the affirmative vote of the holders of at least 66 2/3% of the voting power of the shares of the then outstanding voting stock of the Corporation entitled to vote thereon, voting together as a single class, shall be required to amend, repeal, or adopt any provisions of this Restated Certificate.

* * *

IN WITNESS WHEREOF, this Amended and Restated Certificate of Incorporation has been signed on behalf of the Corporation by its duly authorized officer effective this __ day of _____, 2021.

BLUE WATER VACCINES, INC.

Chief Executive Officer

Exhibit 4.1

INCORPORATED UNDER THE LAWS OF THE STATE OF DELAWARE

Number _____ ***** *Shares*

BLUE WATER VACCINES, INC.

COMMON STOCK

Authorized Capital Stock: Shares

Common Stock: Shares, $0.00001 par value Preferred Stock: Shares, $0.00001 par value

THIS CERTIFIES THAT * * IS THE REGISTERED HOLDER OF (**) SHARES OF THE COMMON STOCK OF

BLUE WATER VACCINES, INC.

HEREINAFTER DESIGNATED "THE CORPORATION," TRANSFERABLE ON THE SHARE REGISTER OF THE CORPORATION UPON SURRENDER OF THIS CERTIFICATE PROPERLY ENDORSED OR ASSIGNED.

A STATEMENT OF THE RIGHTS, PREFERENCES, PRIVILEGES AND RESTRICTIONS GRANTED TO OR IMPOSED UPON THE RESPECTIVE CLASSES OF SHARES OF STOCK OF THE CORPORATION AND UPON THE HOLDERS THEREOF MAY BE OBTAINED BY ANY STOCKHOLDER UPON REQUEST AND WITHOUT CHARGE, AT THE PRINCIPAL OFFICE OF THE CORPORATION.

THE SHARES REPRESENTED HEREBY ARE RESTRICTED TO THE TRANSFER AS DESCRIBED OR SET FORTH ON THE REVERSE SIDE HEREOF.

WITNESS The Seal of the Corporation and the Signatures of its duly authorized officers this day of .

JOSEPH HERNANDEZ, CHIEF EXECUTIVE OFFICER AND DIRECTOR

ERIN HENDERSON, CHIEF BUSINESS OFFICER

FOR VALUE RECEIVED, _____ HEREBY SELL, ASSIGN AND TRANSFER UNTO _____ SHARES REPRESENTED BY THE WITHIN CERTIFICATE AND DO HEREBY IRREVOCABLY CONSTITUTE AND APPOINT _____ ATTORNEY TO TRANSFER THE SAID SHARES ON THE SHARE REGISTER OF THE WITHIN NAMED CORPORATION, WITH FULL POWER OF SUBSTITUTION ON THE PREMISES.

DATED _____, _____

Certain portions of this exhibit have been omitted pursuant to Rule 601(b)(10) of Regulation S-K The omitted information is (i) not material and (ii) would likely cause competitive harm to Blue Water Vaccines, Inc. if publicly disclosed. Information that has been omitted has been noted in this document with a placeholder identified by the mark "[***]".

EXCLUSIVE LICENSE AGREEMENT

THIS EXCLUSIVE LICENSE AGREEMENT (the "Agreement") is made and effective as of June 1, 2021 (the Effective Date") by and between Blue Water Vaccines, having a principal place of business at 201 E Fifth Street, Suite 1900 Cincinnati, OH 45202 ("Company"), and Children's Hospital Medical Center, d/b/a Cincinnati Children's Hospital Medical Center ("CHMC"), having a principal place of business at 3333 Burnet Avenue, Cincinnati, Ohio 45229-3039, USA.

INTRODUCTION

WHEREAS, CHMC owns certain Patents and Technology, as defined in Article 1 of this Agreement, which it desires to make available for the development and commercialization; and

WHEREAS, Company desires to obtain certain license rights to the Patents and Technology; and

WHEREAS, Company has represented to CHMC, to induce CHMC to enter into this Agreement, that Company has the desire, expertise and knowledge to develop, produce, market and sell Products and/or to use Processes and that it will commit itself to a thorough, vigorous and diligent program exploring the Technology and inventions claimed in the Patents such that public benefit from the Processes and/or Products will result.

NOW, THEREFORE, in consideration of the mutual covenants and promises contained in this Agreement and other good and valuable consideration, CHMC and Company agree as follows:

ARTICLE 1 - DEFINITIONS

In the terms defined and used herein, the singular will include the plural and vice versa. Undefined terms in this Agreement (other than names of parties and Article headings) which are set forth in upper case letters have the meanings established for such terms in the succeeding Paragraphs of this Article 1.

1.1 "Affiliate" means, with respect to Company, any corporation, limited liability company or partnership which is controlled by Company. "Control" means that one of the following conditions is met: (a) in the case of corporate entities, direct or indirect ownership of more than fifty percent (50%) of the stock or shares having the right to vote for the election of directors or otherwise to direct or cause the direction of management, and (b) in the case of non-corporate entities, direct or indirect ownership of more than fifty percent (50%) of the equity interest with the power to direct or cause the direction of the management of such non-corporate entities. A company will only be deemed to be an Affiliate for so long as such control exists. Company's Affiliates as of the Effective Date are set forth on Exhibit A to this Agreement.

1.2 "Confidential Information" will have the meaning set forth in Paragraph 11.3.

1.3 "Field of Use" means utilizing the Patents and Technology for all uses other than the Excluded Field

1.4 "Excluded Field" means immunization against, and prevention, control, or reduction in severity of gastroenteritis caused by Rotavirus and Norovirus in China and Hong Kong.

1.5 "Government" means the federal, state and/or local government(s) and regulatory bodies of any country or multinational governmental entities within the Territory.

1.6 "Improvement" means any CHMC Improvements or Company Improvements, as defined in Article 7.

1.7 "Net Sales" means the aggregate invoice sales prices, license fees or other amounts charged by Company, its Affiliates, and its Sublicensees from the sale, lending, lease, license or other distribution or disposal of Products, Processes, Company Improvements, products that use a process that is a Company Improvement, or processes that use a product that is a Company Improvement to third parties in accordance with this Agreement less only credits actually granted on account of regular trade and discount allowances, recalls, rejection or return of items previously sold, all taken in accordance with GAAP. No other deductions will be made in the calculation of Net Sales, including, without limitation, for any commissions, cost of collections, transportation, insurance, storage, or other expenses.

1.8 "New Drug Application" or "NDA" means (i) a New Drug Application as defined in the United States Federal Food, Drug and Cosmetic Act and applicable regulations promulgated thereunder from time to time, and all amendments and supplements thereto filed with the FDA or (ii) the equivalent application, including, without limitation, a marketing authorization application filed with any equivalent agency or governmental authority in the European Union (such as the EMEA) requiring such filing, including all documents, data and other information concerning a pharmaceutical product which are necessary for gaining Regulatory Approval to market and sell such pharmaceutical product.

1.9 "Patents" means the patents and patent applications listed on Exhibit B hereto and any patents maturing from any of the foregoing that are patent applications, and any divisionals, continuations and continuations-in-part (solely to the extent that the claims in such continuations-in-part are directed to subject matter specifically claimed in the Patents listed on Exhibit B, and they have the same priority date of such Patents, but not including any additional or different claims), and the resulting patents therefrom.

1.10 "Phase I Clinical Trials" means a human clinical trial that is designed to determine the metabolism, pharmacologic actions (including pharmacodynamics) and pharmacokinetics of a drug in humans, the safety profile, tolerability and any potential side effects of the drug associated with increasing doses and that satisfies the requirements of 21 CFR 312.21(a), or its successor regulation or its equivalent in any other jurisdiction in the Territory.

1.11 "Phase II Clinical Trials" means a clinical trial that is designed to establish the safety and preliminary efficacy of a drug for its intended use, and to define warnings, precautions and adverse reactions that are associated with the drug in the dosage range to be prescribed and that satisfy the requirements of 21 CFR 312.21(b) (or its successor regulation) or its equivalent in any other jurisdiction in the Territory.

1.12 "Phase III Clinical Trials" means a clinical trial on sufficient numbers of patients that, if the defined end-points are met, are designed (and agreed to by the FDA, or other Regulatory Authorities in the Territory) based upon existing data in the same patient population as of the start of the trial to definitively establish that a drug is safe and efficacious for its intended use, and to define warnings, precautions and adverse reactions that are associated with the drug in the dosage range to be prescribed, and which provide pivotal data supporting Regulatory Approval of such drug or label expansion of such drug and that satisfy the requirements of 21 CFR 321.21(c), or its successor regulation or its equivalent in any other jurisdiction in the Territory.

1.13 "Process" means a process which is disclosed in the Patents or Technology, or a process that uses a product that is disclosed in the Patents or Technology.

1.14 "Product" means a product which is disclosed in the Patents or Technology, or a product which is developed, tested, screened or made in whole or part using a process disclosed in the Patents or Technology.

1.15 **"**Regulatory Approval**"** means any approvals (including supplements, amendments, pre- and post-approvals and price approvals), licenses, registrations or authorizations (including any designations of an indication for a Product as an "Orphan Product" under the Orphan Drug Act), howsoever called, of any Regulatory Authority, which are necessary for the distribution, importation, exportation, manufacture, production, use, storage, transport or clinical testing and/or sale of a Product or Process in a regulatory jurisdiction. Regulatory Approval will not include any site license for a Company manufacturing facility.

1.16 "Regulatory Authority" means the United States Federal Drug Administration ("FDA") or any counterpart of the FDA outside the United States, or other national, supra-national, regional, state or local regulatory agency, department, bureau, commission, council, ethics committee, review board or other entity with authority over the distribution, importation, exportation, manufacture, production, use, storage, transport or clinical testing and/or sale of a Product or Process hereunder.

1.17 "Regulatory Filings" means, collectively, Investigational New Drug applications, Biologics License Applications, NDAs, establishment license applications (ELAs) and drug master files (DMFs), applications for designation of a Product as an "Orphan Product(s)" under the Orphan Drug Act, Orange Book filings, responses to FDA "Written Requests," Premarket Notification 510(k). Premarket Approval (PMA), Investigational Device Exemption (IDE),or any other filings (including any foreign equivalents and further including any related correspondence and discussions), and all data contained therein, as may be required by the FDA or equivalent Regulatory Authorities for the development, manufacture or commercialization of a Product or Process hereunder.

1.18 "Sublicensee" means any business entity other than an Affiliate to whom Company sublicenses the rights set forth in Paragraph 3.2 hereof

1.19 "Technology" means any technical information in existence and known before the Effective Date by CHMC that are necessary for the use or practice of the Patents contemplated hereunder in the Field of Use, solely to the extent. To the extent not patented or otherwise published, the Technology constitutes part of CHMC's Confidential Information.

1.20 "Term" means the period beginning on the Effective Date and extending on a jurisdiction by jurisdiction and product by product basis, the later of:

(i) the last to expire Patent,
(ii) 10 years after the first commercial sale, or
(iii) Entrance onto the market of a biosimilar or interchangeable product

1.21 "Territory" means worldwide.

1.22 "Valid Claim" means a claim of a Patent that: (a) has issued and has not expired, lapsed, been cancelled, or abandoned, or been dedicated to the public, disclaimed, or held unenforceable, invalid, unpatentable, revoked, or cancelled by a court or administrative agency of competent jurisdiction in an order or decision from which no appeal has been or can be taken, including through opposition, reexamination, reissue, disclaimer, inter partes review, post grant review, post grant procedures, or similar proceedings; or (b) is in a pending patent application that has not been abandoned, disclaimed, canceled or finally disallowed without the possibility of appeal or refiling.

ARTICLE 2 - LICENSE

2.1 License Grant. Subject to Company's fulfillment of its payment and other obligations hereunder and CHMC's reservation of rights below, CHMC hereby grants the following to Company during the Term, solely within the Territory and solely in the Field of Use:

2.1.1 Exclusive License: An exclusive license under the Patents to:

(a) Develop, make, lease, sell, license, or otherwise distribute Products; and

(b) Practice the Processes solely as necessary for the exercise of the foregoing rights.

2.1.2 Non-Exclusive License. A non-exclusive limited license to use and copy the Technology internally solely as necessary for the use or practice of the Patents under Sub-Paragraph 2.1.1. CHMC will deliver a copy of the Technology to Company at a time mutually agreed to by the parties and will have no obligation to update the Technology at any later period.

2.2 Reservation of Rights. Notwithstanding the exclusivity of the license in Sub-Paragraph 2.1.1 above, CHMC reserves on behalf of itself and its Affiliates: (a) all rights, titles and interests not expressly granted in the license; and (b) the right to practice, have practiced and transfer the Patents and Technology for research and development purposes, including education, research, teaching, publication and public service. Notwithstanding the foregoing, in no event shall CHMC's use or practice, or permit others to use or practice, the Patents or Technology in the Field of Use for any commercial for profit purpose. For purposes of clarification nothing in this Agreement is intended to or shall be construed to restrict the ability of CHMC to use, practice or permit others to use or practice the Patents or Technology for any purpose except as to the Field of Use. Company is obtaining access to the Patents and Technology but not secrecy thereof.

2.3 Government Funding; Non-Profit Funding. The license rights in this Agreement may also be subject to certain rights of the United States federal and/or state or local Government(s) if the Technology and/or the Patents were created or invented in the course of Government-funded research. Such rights may include, for example, a royalty-free license to the Government and the requirement that any Product produced for sale in the United States will be manufactured substantially in the United States. Company acknowledges such rights and agrees to comply and cause its Affiliates, Sublicensees and agents to comply with all such requirements, including, without limitation, any of those set forth in 35 U.S.C. Section 200 et seq. and regulations pertaining thereto (or any successor statutes or regulations). Moreover, if the Technology and/or the Patents were created or invented in the course of research funded by a research grant from a non-Governmental entity, then the license rights may be subject to the terms of such research grant. If any term of this Agreement fails to conform with the foregoing statutes and regulations or research grant, the relevant term will be unenforceable and subject to the severability provisions in Paragraph 15.5.

2.4 Biological Materials. If the parties desire that CHMC provide Company any patented or unpatented biological or chemical materials in connection with this Agreement, including but not limited to, chemical compounds, animal models, cell lines, cells, nucleic acids, receptors or reagents (collectively, and together with any substance replicated or derived therefrom "Biological Materials"), the parties will execute a separate written non-exclusive license agreement governing the use of such Biological Materials. Upon the expiration or termination of this Agreement, Company will, unless otherwise agreed under the non-exclusive license agreement, either return the Biological Materials to CHMC or destroy them, as instructed by CHMC.

ARTICLE 3 – AFFILIATES; SUBLICENSEES

3.1 Affiliates. As a condition to its receiving the benefits of this Agreement, each Affiliate must first execute and deliver to CHMC a written instrument in form acceptable to CHMC pursuant to which such Affiliate agrees to be bound by all terms and conditions of this Agreement applicable to Company. Company hereby unconditionally guarantees the compliance with and performance by each of its Affiliates of all provisions of this Agreement and will be responsible and jointly and severally liable for all payments due pursuant to this Agreement. A breach of this Agreement by any of Company's Affiliates will also be deemed a breach by Company. Company will provide CHMC with an updated list of all Affiliates from time to time upon CHMC's request.

3.2 Sublicenses. Company may, with the prior written approval of CHMC on a case by case basis, enter into written agreements with Sublicensees granting them sublicenses of Company's rights hereunder to develop, make, lease, sell, license or otherwise distribute Products and practice the Processes consistent with the terms of this Agreement. Each sublicense will be embodied in a written document which (a) contains provisions at least as favorable to CHMC for the protection of its rights and limitation of its liability exposure as the terms of this Agreement, and development and commercialization obligations commensurate in scope as those set forth for Company in this Agreement; (b) contains all rights and obligations due to CHMC contained in this Agreement; (c) names CHMC as a third party beneficiary who may directly enforce the sublicense agreement as if it were a party thereto; and (d) does not permit the Sublicensee to grant further sublicenses. Company will provide CHMC unredacted copies of any executed sublicense agreements and amendments thereto within fifteen (15) days after their execution and an updated list of all Sublicensees from time to time upon CHMC's request. Company will promptly collect all royalties and other amounts due from such Sublicensees and will take appropriate enforcement action against such Sublicensees for any failure to pay or properly calculate payments. Company will not receive or agree to receive anything of value in lieu of monetary consideration from Sublicensees or amend such sublicense agreements without CHMC's prior written consent. All of the terms of this Agreement will apply to each such Sublicensee to the same extent as they apply to Company. Company hereby guarantees the compliance with and performance by each of its Sublicensees of all applicable provisions of this Agreement , and any breach of this Agreement by a Sublicensee will be deemed a breach by Company. No sublicenses will relieve Company of its obligations under Article 4. Any purported sublicenses in violation of this Paragraph will be void. Affiliates will not have a right to grant any sublicenses.

ARTICLE 4 – DUE DILIGENCE

4.1 Company will use commercially reasonable efforts and will cause any Sublicensees or Affiliates to use best efforts (including, without limitation, by commitment of funding and personnel consistent therewith), to bring the Products or Processes to market through thorough, vigorous and diligent programs of research, development, testing, manufacturing, marketing and commercialization and to continue active, diligent efforts for the Products or Processes throughout the Term. Company will use best efforts to make all necessary Regulatory Filings and obtain all necessary Regulatory Approvals. CHMC will have the right, in its discretion, to directly or indirectly participate in any NDA prosecution. Company will notify CHMC in writing within seven (7) days after receiving office notice of any Regulatory Approval. Company will comply with all applicable laws and regulations in connection with all of the foregoing.

4.2 In addition, Company will adhere to the following milestones:

4.2.1 Development and Commercialization Plans; Reports. A preliminary development and commercialization plan ("Plan") will be included herein as Exhibit C. and attached hereto seting under which Company intends to develop, market, use, sell or otherwise commercialize the Products and/or Processes. Company will deliver the Plan o CHMC, within 90 days of the Effective Date. The Plan will set forth each stage of development, the amount of money on hand and committed to an indication, number and kind of personnel and time budgeted for each phase of development of each of the Products or Processes over the next year, and summarizing the development, marketing, manufacturing, sales, and Regulatory Approval progress made since the previous year and will include sufficient detail to allow CHMC to assess whether Company has met its obligations under Paragraph 4.1 to use commercially reasonable efforts and its ability to meet the milestones in Paragraph 4.2.2 below, and will provide similar updated Plans to CHMC on or before January 1 of each year ("Reports"). Company will provide CHMC copies of any similar reports provided by Company's Sublicensees and such other information as CHMC will reasonably request.

4.2.2 Development and Due Diligence Milestones. Company will achieve development milestones as described in the time and events below.

(i) CDMO kick-off Meeting – 9 months after Effective Date
(ii) Pre-IND Meeting – 18 months after Effective Date
(iii) IND filed using Technology – 3 years after Effective Date
(iv) First patient dosed using Technology – 1 year after IND Approval
(v) First BLA or equivalent using Technology – 3 years after IND Approval
(vi) Second BLA or equivalent using Technology – 5 years after IND Approval

4.3 Milestone Notices; Failure. Company will inform CHMC in writing before or within three (3) business days after each milestone deadline whether such milestone has been met. In the event that Company notifies CHMC that it anticipates non-achievement of a certain Milestone or it in fact, has not achieved a certain Milestone for any indications that have already entered development at any stage, then the parties agree to discuss in good faith, for a period of no more than forty-five (45) days, to discuss amending the Milestones. In the event the parties cannot mutually agree on such an amendment, CHMC has the option of converting any or all of such exclusive licenses to nonexclusive licenses with no right to sublicense and no right to initiate legal proceedings. In the event CHMC converts such exclusive licenses to nonexclusive licenses, Company continues to be bound by all payment obligations under Article 8. Company's failure to tomeet any of the milestone payment obligations in Paragraph 8.5 will be grounds for CHMC to terminate this Agreement for material breach.

ARTICLE 5 - PATENT PROSECUTION AND COSTS

5.1 Patent Prosecution and Maintenance. CHMC will have the first and sole right, using in-house or outside legal counsel selected by CHMC, to prepare, file, prosecute, maintain and extend patents and patent applications in the Patents in its own name in the United States of America and in any other countries in the Territory, and Company agrees to reimburse CHMC for its legal and administrative costs (including, without limitation, outside attorneys' fees, filing fees and maintenance fees) incurred under this Paragraph within thirty (30) days after each receipt of CHMC's written statement of such expenses. Without limiting the materiality of any other breaches, Company's failure to do so will be a material breach of this Agreement. CHMC will use reasonable efforts to deliver to Company reasonably complete drafts of all material submissions to patent authorities relating to the Patents, including, without limitation, patent applications and amendments, and, to the extent feasible, to give Company a reasonable opportunity to comment on such documents prior to their filing. Company will provide any such comments promptly. CHMC will consider Company's comments and requests with regard to the preparation, filing, prosecution and/or maintenance of the Patents in good faith. However, the final decision with respect to such matter will remain with CHMC. CHMC will also provide Company copies of material documents received from such patent authorities relating to the Patents. If CHMC notifies Company of its proposal to file a Patent hereunder in any country in the Territory and Company notifies CHMC in writing within fourteen (14) days thereafter that it does not agree to such filing, then CHMC will have the right to file, prosecute and maintain such Patent in such country at its own expense, and such Patent will not be included in Company's license under this Agreement.

5.2 Company's Election to Prosecute. In the event that CHMC desires not to remain responsible for the prosecution or maintenance of any Patents, it will provide Company with sixty (60) days' written notice of such intended decline of responsibility, and Company may, upon written notice, elect to assume, at Company's expense, the responsibilities and obligations to prosecute, and maintain and extend in CHMC's name the abandoned Patents in their respective countries. Company will use reasonable efforts to deliver to CHMC reasonably complete drafts of all material submissions to patent authorities relating to the Patents, including, without limitation, patent applications and amendments, and, to the extent feasible, to give CHMC a reasonable opportunity to comment on such documents prior to their filing. CHMC will provide any such comments promptly. Company will consider CHMC's comments and requests with regard to the preparation, filing, prosecution and/or maintenance of such abandoned Patents in good faith. However, the final decision with respect to such matter will remain with Company. Company will also provide CHMC copies of material documents received from such patent authorities relating to the Patents.

5.3 Company's Abandonment. If, after electing to assume the responsibilities set forth in Paragraph 5.2 above, Company subsequently determines not to prosecute or maintain such Patents in any country, Company will provide CHMC with sixty (60) days' written notice ("Abandonment Notice"). If the Territory includes multiple countries and such determination is made on a country-by-country basis, then upon Company's Abandonment Notice to CHMC, Company's license and other rights hereunder will terminate with respect to such country/countries and CHMC will have the right but not the obligation to assume responsibility for the prosecution and maintenance in such country/countries and will be responsible for all expenses associated therewith.

ARTICLE 6 - PUBLICATION RIGHTS

6.1 CHMC reserves the right for itself and its Affiliates and investigators to present, publish or otherwise disseminate the results of its and their research on the inventions claimed in the Patents and Technology. However, CHMC agrees to submit copies of any abstract or manuscript proposed for written or oral presentation or publication regarding the inventions claimed in the Patents to Company at least thirty (30) days in advance of the submission or presentation. If Company does not, within thirty (30) days after receipt of the manuscript, object in writing, CHMC may proceed with the presentation or publication. However, if Company notifies CHMC in writing within such period that it has a reasonable belief that such presentation or publication would reveal Company's own Confidential Information or a patentable invention for which patent applications are being filed under Article 5, it will provide a written request to CHMC specifically identifying the information giving rise to the belief. CHMC will consider Company's request in good faith. If it agrees with Company, it will, as applicable, either remove Company's Confidential Information or not publish or present the information so identified by Company until such time as a patent application has been filed or the expiration of sixty (60) days after the date of submission of the manuscript or abstract to Company, whichever occurs first. Company will keep all submissions made by CHMC hereunder confidential in accordance with Article 11 until such time as CHMC or its Affiliates or investigators make the applicable publication or presentation.

ARTICLE 7 – OWNERSHIP; IMPROVEMENTS

7.1 Ownership. CHMC is and will remain the sole owner of the Patents, Technology, CHMC Improvements and Biological Materials, as well as any other current or future patent, copyright, trade secret, database rights or other intellectual property rights in any of the foregoing in any country. Company agrees to execute any additional documents and do all things necessary or appropriate, during and after the Term of this Agreement, to vest and confirm all such rights in CHMC to any of the foregoing and to facilitate the obtaining by CHMC of any desired legal protection for the same in any countries. Any documents or actions described in the preceding sentence will be prepared, filed or taken at CHMC's expense, but Company will sign such documents and otherwise cooperate at no cost to CHMC.

7.2 Patent Marking. To the extent commercially feasible, Company will mark all Products with the number of each issued Patent(s) that cover(s) the Products. Any such marking will be in conformance with the patent laws and other laws of the country of manufacture, use or sale, as applicable.

7.3 Contesting the Patents. To the fullest extent permitted by law in the countries within the Territory, in the event that Company or its Affiliates contest the validity or enforceability of any of the Patents granted under the laws of such country, or set up or induce the setting up of any adverse allegations as to the validity or enforceability thereof, or lend their aid and support of any opposition thereto, then CHMC will have the right to terminate this Agreement immediately upon written notice to Company, and Company will reimburse CHMC for its costs (including, without limitation, reasonable attorneys' fees) of defending any such allegations of invalidity or enforceability.

7.4 Notification of Improvements. Each party agrees to promptly disclose their respective Improvements in writing to the other party after they have first been reduced to practice and patent applications have been filed on them to the extent lawfully permitted to do so without breaching any restrictions on use or disclosure owed to third parties, and will promptly advise the other party of the filing and maintenance of any patent or application on the same.

7.5 "CHMC Improvement" means any patented modification, alteration or improvement of any invention claimed in a Patent and which is conceived of or reduced to practice by one or more employees or agents (including, without limitation, consultants or contractors) of CHMC after the Effective Date and is assigned to CHMC, and excluding any Joint Improvements as defined in Section 7.7. CHMC Improvements will not be included in the license grants set forth in this Agreement. Provided that a CHMC Improvement is not encumbered by an agreement with a third party that would preclude so adding it, CHMC hereby grants to Company an exclusive option to add CHMC Improvements to the license rights granted in this Agreement for sixty (60) days after Company has been notified of the existence of each such CHMC Improvement under Paragraph 7.4 (an "Option Period"). CHMC will notify Company in writing of the option fee, as indicated in section 8.3, and patent costs to be reimbursed by Company, if any, as determined by CHMC, to add such CHMC Improvement. Company may exercise its option to add such CHMC Improvement by providing CHMC, within the relevant Option Period, with written notification of Company's desire to so add the CHMC Improvement and paying CHMC the option fee and patent costs for each CHMC Improvement so added, in which case, such CHMC Improvement will be subject to the same restrictions, limitations, warranty disclaimers, and obligations herein as the Patents, including, without limitation, the payment of Running Royalties.

7.6 “Company Improvement” means any modification, alteration or improvement of any invention disclosed in Technology or a Patent which is conceived of or reduced to practice solely by one or more employees or agents (including, without limitation, consultants or contractors) of Company or Affiliates or Sublicensees. CHMC will automatically have a worldwide, perpetual, sublicenseable, non-exclusive, paid up, royalty-free license to use any Company Improvements solely for clinical or non-clinical, non-commercial research, testing, educational and patient care purposes. Company agrees to execute and deliver at no charge any additional documents reasonably requested by CHMC to confirm such non-exclusive license.

7.7 “Joint Improvement” means any patented modification, alteration or improvement of any invention claimed in a Patent and which is conceived of or reduced to practice jointly by one or more employees or agents (including, without limitation, consultants or contractors) of CHMC and one or more employees or agents (including, without limitation, consultants or contractors) of Company or Affiliates or Sublicensees after the Effective Date and is assigned according to the inventorship obligations of each inventor. Joint Improvements will not be included in the license grants set forth in this Agreement. Provided that a Joint Improvement is not encumbered by an agreement with a third party that would preclude so adding it, CHMC hereby grants to Company an exclusive option to add Joint Improvements to the license rights granted in this Agreement for sixty (60) days after Company has been notified of the existence of each such Joint Improvement under Paragraph 7.4 (an "Option Period"). CHMC will notify Company in writing of the option fee, as indicated in section 8.3, and patent costs to be reimbursed by Company, if any, as determined by CHMC, to add Joint Improvement. Company may exercise its option to add such Joint Improvement by providing CHMC, within the relevant Option Period, with written notification of Company's desire to so add the CHMC Improvement and paying CHMC the option fee and patent costs for each Joint Improvement so added, in which case, such Joint Improvement will be subject to the same restrictions, limitations, warranty disclaimers, and obligations herein as the Patents, including, without limitation, the payment of Running Royalties.

7.8 Compulsory Licensing. During the Term, CHMC may become aware of Third Parties that are interested in obtaining rights to the Products or Processes for specific indications not indicated in a Report as defined in Section 4.2.1 (each such specific indication being a "New Indication"). CHMC will provide notice to Company of any written indications of interest in a New Indication (including, without limitation, the written notice of interest from, and the name and contact details of, any such Third Party (each an "Interested Third Party") and the specified New Indication) within thirty (30) days of receipt of such written indication of interest (a "New Indication Notice"). Company will then provide written notice to CHMC within thirty (30) days of receipt of a New Indication Notice of its decision regarding the development of such New Indication.

7.8.1 If Company elects to develop the Products or Processes in respect of the New Indication, the Parties will negotiate commercially reasonable development targets to be pursued by Company under this Section (the "New Indication Development Period"). If, upon expiration of the New Indication Development Period, Company has not met the development targets, then the relevant New Indication shall be added to the Excluded Field;

7.8.2 If Company elects not to develop the Products or Processes in respect of the New Indication then:

(i) Company may at its sole discretion elect to enter into good faith negotiations with the relevant Interested Third Party for the grant of a sublicense under the Products or Processes in respect of the relevant New Indication, and Company shall keep CHMC reasonably informed of such negotiations with CHMC able to join in discussions with Company and the Interested Third Party at CHMC's discretion; or

(ii) if Company has not within three (3) months of the New Indication Notice entered into good faith negotiations, such New Indication will be excluded from the license grant and CHMC will be free to pursue licensing of the Products or Processes within each excluded field to the Interested Third Party.

ARTICLE 8 - PAYMENTS AND ROYALTIES

In consideration of the rights set forth herein, Company will make the following payments to CHMC:

8.1 Initial License Fee. Upon execution of this Agreement, Company will pay to CHMC a one-time, non-refundable, non-creditable license fee ("Initial License Fee") of Twenty-five Thousand Dollars (US ***[***]***), payable within thirty (30) calendar day of the Effective Date.

8.2 Deferred License Fees:

(i) A deferred license fee of ***[***]*** is payable upon Company's first to occur convertible debt or equity raise after the Effective Date. At Company's option, payment of the accrued patent expenses due as of the Effective Date can be made in the form of that convertible debt or equity to CHMC with the same terms and conditions as the other investors for that fund raise event.

(ii) In addition, separate deferred license fee of ***[***]*** is payable upon the one year anniversary of the Effective Date.

8.3 Improvements License Fees: For each Improvement that Company elects to include in the License Grant as described in Sections 7.5 and 7.7, Company shall pay a option fee of ***[***]*** within thirty (30) calendar days of notifying CHMC that the Company exercises the Option to license such Improvement.

8.4 Patent and Legal Fees. Company will also pay CHMC for all past patent and legal fees associated with the Patents, totaling ***[***]*** as of the Effective Date. Such payments will be made to CHMC within thirty (30) calendar days after the Company's first to occur convertible debt or equity raise following the Effective Date. At Company's option, payment of the accrued patent expenses due as of the Effective Date can be made in the form of that convertible debt or equity to CHMC with the same terms and conditions as the other investors for that fund raise event. As of the Effective Date, Company will be responsible for all current and on-going patent expenses and will reimburse CHMC for such expenses promptly upon receipt of invoice.

8.5 Milestone Payments. Upon completion of each milestone described below, Company will pay CHMC as follows:

(i) IND filing of Licensed Product - ***[***]***

(ii) BLA or equivalent allowed for Licensed Product in US or EU - ***[***]***

(iii) First commercial sale of Licensed Product in US - ***[***]***

(iv) First commercial sale of Licensed Product in EU - ***[***]***

(v) First Commercial sale of Licensed Product in Japan - ***[***]***

(vi) First Commercial sale in ROW - ***[***]***

(vii) Conclusion of first calendar year in which aggregate Net Sales of Licensed Product(s) exceed $250,000,000 - ***[***]***

(viii) Conclusion of first calendar year in which aggregate Net Sales of Licensed Product(s) exceed $500,000,000 - ***[***]***

(ix) Conclusion of first calendar year in which aggregate Net Sales of Licensed Products(s) exceed $1,000,000,000 - ***[***]***

8.6 Running Royalties. Beginning on first Net Sale, Company will pay CHMC running royalties ("Running Royalties") on a quarterly basis a percentage of Net Sales of Company, its Affiliates, and its Sublicensees for the previous quarter as follows:

(i) while there exists a Valid Claim:

a. 5% for Products or Processes for P-Particle VLP Bi-valent vaccine for norovirus and rotavirus,

b. 4% on Products or Processes for Universal Flu Vaccine(s),

c. 2% on Products or Processes for all other indications

(ii) while no Valid Claim exits, 50% of the applicable running royalty rate as outlined in above Subsction 8.6(i)

So long as the quarterly payment is more than ***[***]***, each payment of Running Royalties will be made within thirty (30) days after the end of each quarter. If the payment is ***[***]*** or less, then payment can be delayed until the sum of the amount due reaches ***[***]***. Regardless, within thirty (30) days after the end of each quarter, Company will provide a report of Net Sales in sufficient detail to permit confirmation of the accuracy of the Running Royalty payment made, including, without limitation and on a country-by-country basis, the number of Products sold or Processes commercialized, the gross sales and Net Sales and deductions taken from gross sales by category as set forth in the definition of Net Sales to arrive at the Net Sales calculation, the Running Royalties payable (in U.S. Dollars), and the method used to calculate the Running Royalties as well as the exchange rates used, if applicable. If the gross sales or Net Sales per Product or Process varies between customers or payors of the Products or Processes, Company shall further include details, grouped by the differing gross sales or Net Sales per Product or Process, as to the number of Products sold or Processes commercialized, the gross sales and Net Sales and deductions taken from gross sales by category as set forth in the definition of Net Sales to arrive at the Net Sales calculation.

8.6.1 Anti-Stacking Provision. In the event that Company is legally required to make royalty payments to one or more third parties whose patent rights dominate the Patent(s) and would therefore be infringed by the exercise of the license rights granted in Paragraph 2.1, or whose patent rights Company is required to license to obtain Regulatory Approval to sell Product, Company may reduce Running Royalties due to CHMC in the same quarterly reporting period by fifty percent (50%), provided, however, that in no event shall the Running Royalties be reduced below half of the applicable Running Royalty in Subections 8.6(i) and (ii) in any quarterly reporting period. In order to exercise its offset rights hereunder, Company must send written notice to CHMC describing the nature and amount of its payment requirements, the identity of the third party and the applicable third party patents promptly after first becoming aware of the requirement to make any such payments. In no event will Company be eligible to reduce the Running Royalties as described in this Paragraph for any payments required to be made by Company to use any third party biological research tools.

8.7 Consideration other than Monetary. Company and its Affiliates and Sublicensees will have no right to sell, license or otherwise distribute Products or commercialize Processes for no consideration or in exchange for non-monetary compensation without CHMC's prior written consent. Upon any such approved sale, license or other distribution or disposal other than for monetary consideration or at a discounted price substantially lower than the customary price, such Product will be deemed to be sold or Process used exclusively for money at the average price during the applicable reporting period generally achieved in arms' length transactions for such Product or Process in the country in which such sale, license or other distribution or disposal occurred when such Product is sold or Process used alone and not with other products (or, in the absence of such sales or licenses, at the fair market value of the Product or Process).

8.8 Sublicenses. In the event that Company enters into a sublicense agreement with a Sublicensee, Company will pay to CHMC a percentage of all non-royalty sublicensing revenues received from said Sublicensee (including, without limitation, license fees, milestone payments, advances, license maintenance fees, and other payments) as follows:

(i) Twenty-five percent (25%) for revenue received prior to first Net Sale of first Licensed Product, or

(ii) ***[***]*** for revenue received after first Net Sales of first Licensed Product but before first Net Sales of second Licensed Product, or

(iii) ***[***]*** for revenue received after first Net Sales of second Licensed Product.

Payments to CHMC with respect to sublicense revenue and royalties will be due within thirty (30) calendar days after such amounts are received by Company.

8.9 Taxes and Other Fees. In addition to any other amounts due hereunder, Company will pay, without any deduction to its Net Sales, all federal, state, municipal, foreign, and other governmental excise, sales, use, property, customs, import, value added and other taxes, fees and levies of any nature that are assessed upon or with respect to the development, manufacture, use, offer, sale, license distribution, export or import of the Technology, Products or Processes or otherwise arising in connection with this Agreement, other than United States taxes based on CHMC's income. If any withholding tax is imposed under the laws of a country or other taxing jurisdiction outside of the United States on any amounts to be paid to CHMC, such amounts will be increased by the amount of the withholding tax. Company will be solely responsible for and will pay any and all amounts required in the foreign location to be withheld, charged, deducted, or assessed against such payment amounts and will promptly furnish CHMC with certificates evidencing payment of such amounts.

8.10 Payments; Currency. All payments under this Agreement will be made by wire transfer as per the following instructions:

Bank Name: PNC Bancorp
Bank Address: 201 East Fifth Street, Cincinnati, OH 45202

ABA Number: 041000124
Swift Code (aka BIC Code): PNCCUS33

Account Name: Children's Hospital Medical Center
Account Number: 4006905247

Attention: Center for Technology Commercialization, Business Manager
Reference: CHMC REF# LIC210501

Each wire transfer will identify the obligation under this Agreement that the payment satisfies. All payments will be made in U.S. Dollars without set-off for currency conversion. With respect to Net Sales invoiced or expenses incurred in a currency other than U.S. Dollars, the Net Sales invoiced or expenses incurred will be converted into the US Dollar equivalent using a conversion rate existing in the United States (as reported in the Wall Street Journal) on the last working day of the applicable reporting/payment period.

8.11 Unpaid Amounts; Interest; Material Breach. Any sums which have not been timely paid by Company will accrue interest compounded daily from the original due date of each sum until the date of actual receipt of payment at the annual rate of ten percent (10%) or the maximum rate allowable by law, whichever is higher. Without limiting the materiality of any other breaches of this Agreement, Company's failure to make timely payments under this Article 8 will be deemed a material breach.

8.12 Records; Audit. Company will keep during the Term and for a period of three (3) years thereafter, full, true and accurate books of accounts and other records containing all information necessary to ascertain and verify the remuneration payable to CHMC hereunder. During the Term of this Agreement and for three (3) years thereafter, CHMC will have the right to audit, or have an agent, accountant or other representative, audit such books, records and all other material documentation of CHMC and its Affiliates and Sublicensees relating to Net Sales and other payment obligations at reasonable times and upon reasonable notice. Should the audit lead to the discovery of a discrepancy to CHMC's detriment, Company will pay the amount of the discrepancy, plus interest, within thirty (30) days of Company's written notice with the findings of the inspection. CHMC will pay the full cost of the inspection unless the discrepancy is greater than five percent (5%) to CHMC's detriment, in which case Company will pay the reasonable cost charged by such accountant for such inspection at the time of payment of the discrepancy.

8.13 Blocked Payments. If by law, regulation, or fiscal policy of a particular Government, conversion into United States Dollars or transfer of funds of a convertible currency to the United States is restricted or forbidden ("Blocked Payments"), Company will give CHMC prompt notice in writing and will pay the Blocked Payments through such means or methods as are lawful in such country as CHMC may reasonably designate. Failing the designation by CHMC of such lawful means or methods within thirty (30) days after such notice is given to CHMC, Company will deposit such Blocked Payments in local currency to the credit of CHMC in a recognized banking institution reasonably selected by Company and identified in a written notice to CHMC by Company.

ARTICLE 9 - INFRINGEMENT

9.1 Notification. Each party will promptly report in writing to the other party during the Term any infringement or suspected infringement in the Territory of any Patent of which it becomes aware and will provide the other party with all available evidence supporting such infringement or suspected infringement.

9.2 Joint Suit. If CHMC and Company agree in writing to jointly institute a suit against any third party who has infringed or is suspected of infringing any of the Patents licensed hereunder within the Field of Use in the Territory, then the suit will be brought in the name of both parties. The parties will agree in writing on who will control the action and how costs and recoveries will be shared. If the parties agree that Company will control the action, then CHMC may, if it so desires, be represented by counsel of its own selection and at its own expense.

9.3 CHMC Infringement Suit. Absent written agreement as set forth above, CHMC will have the first and sole right, but not the obligation, at its own expense to initiate an infringement suit or other appropriate action against any third party who at any time has infringed or is suspected of infringing any of the Patents licensed hereunder. CHMC will provide Company with an opportunity to make suggestions and comments regarding such action; however, all final decisions will be made by CHMC in its discretion. CHMC will keep Company promptly informed of the status of any such action. CHMC may join Company to the suit at its option, provided that CHMC will bear all of Company's litigation-related expenses and out-of-pocket expenses, including, without limitation, reasonable attorney fees. Otherwise, Company will offer reasonable assistance to CHMC in connection with such action at no charge to Company except for the reimbursement of reasonable out-of-pocket expenses in connection with such assistance, including attorneys' fees. Any damages, profits, or awards of whatever nature recovered from such action will belong solely to CHMC.

9.4 Company Infringement Suit. In the event that CHMC does not, within six (6) months after becoming aware of the infringement, secure cessation of the infringement, enter suit against the infringer or provide Company with evidence of the pendency of a bona fide negotiation for the acceptance by the infringer of a sublicense under the Patents, then to the extent that its license rights are then exclusive, Company will have the right at its own expense to initiate an infringement suit against such infringer if and only to the extent that the infringement is in the Territory and the Field of Use and adversely and substantially affects Company's exclusive license rights. Company may join CHMC to the suit, upon CHMC's approval which will not be unreasonably withheld. If CHMC is joined, Company will bear all of CHMC's litigation-related expenses and out-of-pocket expenses in connection with such assistance, including, without limitation, reasonable attorney fees. Otherwise, CHMC will offer reasonable assistance to Company at no charge to Company except that Company will reimburse CHMC for all of its reasonable out-of-pocket expenses, including attorney fees. Company will give CHMC sufficient advance written notice of its intent to initiate or not initiate any such action and the reasons therefor and will provide CHMC with an opportunity to make suggestions and comments regarding such action; however, all final decisions will be made by Company in its discretion. Notwithstanding the foregoing, CHMC will also independently have the right to voluntarily join the suit, in which case CHMC will pay one half of the cost of prosecuting the lawsuit from the date of joining. Company will keep CHMC promptly informed of the status of any such action. Any damages, profits or awards of whatever nature recovered from such action will be treated as Net Sales under this Agreement after Company has been compensated for its costs in handling such action hereunder and also after CHMC has been compensated for its costs in handling such action if CHMC joins the suit. Company will have no right or authority to settle or otherwise voluntarily dispose of any such action without CHMC's prior written consent, not to be unreasonably withheld, except that Company may grant a sublicense to any alleged infringer in accordance with the terms and conditions of this Agreement relating to sublicenses. Any upfront fees, royalties and other revenues delivered to Company pursuant to such sublicense will be treated as set forth in Paragraph 8.8.

9.5 Abandonment of Suit. In the event that either party institutes a suit under this Article and then decides to abandon the suit, it will first provide timely written notice to the other party of its intention to abandon the suit, and the other party, if it wishes, may continue prosecution of such suit, provided however, that the sharing of expenses and of any recovery in such suit will be agreed upon separately in good faith by the parties taking into account their respective efforts in the prosecution.

9.6 Third Party Suit. In the event that a third party institutes a suit against Company for infringement, Company will promptly inform CHMC and keep CHMC regularly informed of the proceedings. In the event that such third party institutes a suit against CHMC or CHMC is joined as a party, CHMC will have the right to control the defense of the suit.

9.7 Declaratory Judgment Actions. In the event that a declaratory judgment action is brought against Company by a third party alleging invalidity or unenforceability, or non-infringement of the Patents, CHMC, at its option, will have the right in its discretion within thirty (30) days after receiving notice of the commencement of such action to intervene and participate at its own expense or to take over sole control of the defense of the action at its own expense. In any case, the party controlling the defense will provide to the other party each document or a draft thereof pertaining to the declaratory judgment action, including, but not limited to, each communication with opposing counsel, pleading, discovery requires, or other court filing, as follows: (a) documents received from the court or opposing counsel will be provided promptly after receipt; and (b) for a document to be served on opposing counsel or filed in court, a draft of such document will be provided to the non-controlling party sufficiently in advance of its filing to allow for review and comment by the non-controlling party. The controlling party agrees to consider the non-controlling party's comments in good faith but will have the right to make all decisions in its sole discretion.

ARTICLE 10 - WARRANTY DISCLAIMER

10.1 Nothing in this Agreement will be construed as:

(a) A warranty or representation by CHMC as to the validity or scope of any Patent or that any pending patent applications under the Patents will issue;

(b) A warranty or representation that anything made, used, sold or otherwise disposed of under any license granted in this Agreement is or will be free from infringement of patents, copyrights, trade secrets or other intellectual property of third parties;

(c) An obligation of CHMC to bring or prosecute actions or suits against third parties for infringement;

(d) Granting by implication, estoppel or otherwise any licenses under patents of CHMC other than Patents; or

(e) An obligation to furnish any technology, technological information or other materials other than as expressly identified herein.

10.2 CHMC MAKES NO, AND HAS NOT MADE ANY, REPRESENTATIONS OR WARRANTIES OF ANY KIND, EITHER EXPRESS OR IMPLIED, AND ASSUMES NO RESPONSIBILITIES OR LIABILITY WHATSOEVER WITH RESPECT TO THE PATENTS, TECHNOLOGY OR BIOLOGICAL MATERIALS OR THE USE, SALE OR OTHER DISPOSITION BY COMPANY OR ITS AFFILIATES, SUBLICENSEES, VENDEES OR OTHER AGENTS OR TRANSFEREES OR END USERS OF PRODUCTS OR PROCESSES INCORPORATING OR MADE BY USE OF ANY TECHNOLOGY OR PATENTS LICENSED UNDER THIS AGREEMENT OR BIOLOGICAL MATERIALS (IF ANY), FURNISHED IN CONNECTION WITH THIS AGREEMENT. THE FOREGOING ARE PROVIDED AS IS, WITHOUT WARRANTY OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE OR ANY OTHER WARRANTY, EXPRESS OR IMPLIED, AND COMPANY WAIVES ALL RIGHTS TO MAKE ANY CLAIM WHATSOEVER AGAINST CHMC WITH RESPECT TO ANY OF THE FOREGOING. COMPANY SHALL BE SOLELY RESPONSIBLE FOR ALL REPRESENTATIONS AND WARRANTIES THAT COMPANY OR ITS AGENTS, SUBLICENSEES OR AFFILIATES MAKE TO THIRD PARTIES WITH RESPECT TO ANY OF THE FOREGOING.

ARTICLE 11 – PUBLICITY; MARKS; CONFIDENTIALITY

11.1 Publicity. Neither party will make any public press release or similar publicity announcement or disclosure regarding this Agreement without the other party's prior written consent. The disclosing party will provide copies of the proposed disclosure reasonably in advance (but in no event less than fifteen (15) business days) of such release or announcement for the non-disclosing party's prior review and comment. The non-disclosing party will provide its comments, if any, on such announcement as soon as practicable. Notwithstanding the foregoing, either party will be permitted, without the need for consent, to make an objective statement that this Agreement exists, without revealing its terms and conditions.

11.2 Use of Names, Logos or Symbols. No rights are granted in or to CHMC's or its Affiliates' names, logos, trademarks or service marks (including, without limitation, the names "Cincinnati Children's Hospital Medical Center," "CHMC," "Cincinnati Children's Research Foundation" or "CCRF"), or the physical likeness or names of its employees or investigators or other symbols of CHMC or its Affiliates for any purpose without its prior written consent, other than as approved under Paragraph 11.1 above.

11.3 Confidential Information. For purposes of this Agreement, Confidential Information means any non-public information or materials of a party hereto which the other party is provided or has access to hereunder that relate to the transmitting party's research or business, or the Patents, Technology or Biological Materials, and which are either identified as confidential at the time of disclosure or should, under the circumstances, reasonably be expected to be confidential such as test data, samples, data, drawings, trade secrets, draft and final correspondence with the United States Patent and Trademark Office and other patent authorities, and the terms of this Agreement, but does not include materials or information that the receiving party can, prior to its proposed use or disclosure, substantiate through written documentation: (a) is explicitly approved for release by the transmitting party; (b) was already known by the receiving party prior to receiving the information or material from the transmitting party; (c) was lawfully disclosed to the receiving party by a third party having the right to disclose it without an obligation of confidentiality; (d) was in the public domain at the time of disclosure or later become part of the public domain through no fault or breach of obligation by the receiving party, its employees, or agents; or (e) was independently developed by the receiving party without use of the disclosing party's Confidential Information.

11.4 Confidentiality Obligations. Each party agrees to maintain such Confidential Information received from the other party in strict confidence, to use it only in a manner consistent with the purpose for which it was transmitted and to not disclose it to third parties except third parties who are counsel or who are employees, consultants or permitted contractors or subcontractors of the receiving party who have a need to know, have been instructed that it is proprietary information and are under binding obligations to maintain its confidentiality pursuant to terms which are at least as stringent as those set forth herein. Each party agrees to take the same measures to protect the Confidential Information of the other party that it takes to protect its own information of comparable sensitivity, but in no event less than reasonable care. All materials transmitted between the parties or accessed hereunder and containing Confidential Information will remain the property of the transmitting party and will, along with all copies, summaries and other tangible manifestations thereof, be immediately returned upon termination or expiration of this Agreement or upon earlier reasonable request unless previously destroyed at the transmitting party's request. Each party will, upon the other party's request, provide a written officer's certificate certifying that it has so returned or destroyed the other party's Confidential Information. Each party will be responsible for any breach of confidentiality hereunder by any of its Affiliates, Sublicensees, consultants, employees, independent contractors. Each party will advise the other immediately in the event that it learns or has reason to believe that any person discloses or uses or intends to disclose or use such other party's Confidential Information and will reasonably cooperate with the other party to prevent or remedy the same.

11.5 Required Disclosures. Notwithstanding the foregoing, CHMC and Company may disclose each other's Confidential Information to the extent that it is required to be disclosed by law or regulation or is reasonably required to be disclosed in order to enforce rights under the Agreement, provided that the receiving party will, if reasonably possible, notify the other party of the intended disclosure in advance, reasonably cooperate with the disclosing party's effort to seek a protective order contesting or limiting the disclosure and limit its disclosure to that which is required for the foregoing purpose. CHMC may also disclose the terms and conditions of this Agreement to the Government and its agents as necessary in connection with any Government funding related to the Patent rights or Technology.

11.6 Duration of Confidentiality Obligations. Notwithstanding the expiration or termination of this Agreement, the parties' respective confidentiality obligations will continue in effect for ten (10) years after the expiration or termination of this Agreement.

11.7 Remedies. The parties each acknowledge and agree that a breach of this Article 11 may cause irreparable harm to the non-breaching party for which the award of money damages may be inadequate. The parties therefore agree that in the event of any breach of this provision, the non-breaching party will be entitled to seek injunctive relief in addition to seeking any other remedy provided in this Agreement or available at law.

ARTICLE 12 - TERMINATION

12.1 For Convenience. Company may terminate this Agreement at any time prior to first commercial sale of a Product or Process by providing at least one hundred and eighty (180) days' written notice to CHMC.

12.2 For Breach.

12.2.1 In the event that Company breaches any of its material obligations hereunder, CHMC may at its sole option and discretion terminate this Agreement, provided that CHMC will have first given Company written notice specifying the nature of the breach and Company will have failed to cure such breach within thirty (30) days thereafter. If Company has begun to cure such breach and is diligently pursuing its cure if such breach is curable, but is not capable of being cured within thirty (30) days of such notice, then CHMC shall not exercise its termination rights for an additional sixty (60) day period.

12.2.2 Subject to Section 4.3 and Section 12.2.3, n the event that CHMC breaches any of its material obligations hereunder, Company may, upon written notice, terminate this Agreement, provided that it will have first given CHMC written notice specifying the nature of the breach and CHMC will have failed to cure such breach within thirty (30) days thereafter. If CHMC has begun to cure such breach and is diligently pursuing its cure if such breach is curable, but is not capable of being cured within thirty (30) days of such notice, then Company shall agree to give CHMC an additional sixty (60) day period to cure such breach.

12.2.3 In the event Company's material breach is related to failure to meet Milestones under Section 4.2.2, Company is entitled to a nonexclusive license under Section 4.3, to continue to develop indications that have already entered development at any stage or in which Company has invested in developing.

12.3 For Company's Bankruptcy or Insolvency. CHMC may also terminate this Agreement by written notice to Company upon Company's (i) becoming insolvent or otherwise unable to pay its debts as they become due (unless Company cures such condition within thirty (30) days after receipt of written notice of a claim of insolvency by CHMC); (ii) making a general assignment for the benefit of its creditors; or (iii) becoming the subject of a voluntary or involuntary petition in bankruptcy or any voluntary or involuntary proceeding relating to receivership, liquidation, or composition for benefit of creditors under domestic or foreign bankruptcy or insolvency law.

12.4 Effect on Sublicenses. Termination of this Agreement will automatically terminate all sublicenses which may have been granted by Company.

12.5 General Effect of Termination; Survival. Upon expiration or termination of this Agreement, neither party will be relieved of any obligations incurred prior to such termination, and the obligations of the parties under any provisions which by their nature are intended to survive any such termination will survive and continue to be enforceable, including, without limitation, those related to confidentiality, indemnification, limitation of liability, exclusion of damages and payments then due. Company will provide CHMC with all information and data in its possession or control as of the termination date that is reasonably necessary for CHMC to continue to pursue the development of Products and Processes, and CHMC or its agents or licensees will have a right to reference Company's regulatory filings. Termination or expiration of this Agreement for any reason will not preclude any party from pursuing all rights and remedies it may have hereunder or at law or in equity with respect to any breach of this Agreement.

ARTICLE 13 – INDEMNIFICATION; INSURANCE; LIMITATION OF LIABILITY

13.1 Indemnification. Company will, at its sole expense, defend CHMC and its Affiliates, and its and their agents, directors, trustees, officers and employees (or anyone of them) against all claims, suits, actions, demands, judgments, or investigations (both governmental and non-governmental), and will indemnify, release and hold them harmless from and against any and all losses, damages, fees, liabilities, penalties or expenses (including, without limitation, reasonable attorneys' fees) incurred, assessed or awarded, under any theory of liability, including, without limitation, tort, warranty or strict liability, arising out of or in connection with (i) the development, manufacture, use, commercialization, packaging, marketing or sale, lease, license or other distribution or disposition by Company and its Sublicensees and Affiliates or any of their agents of any Product and/or Process hereunder, (ii) the use by Company or its Sublicensees or Affiliates or any of their agents or transferees of Technology, Biological Materials or Patents, or the use, sale or other disposition by Company or its Sublicensees or Affiliates or any of their agents or transferees of Products or Processes; (iii) any representation or warranty made by Company or its Sublicensees or Affiliates or agents to third parties with respect to the Patents, Technology, Products or Processes; (iv) any claims for death, illness or personal injury caused by the Products and/or Processes; or (v) any asserted violation by Company or its Sublicensees or Affiliates or any of their agents of any Export Laws or other applicable laws or regulations. Company also will reimburse CHMC for its expenses, including, without limitation, reasonable attorneys' fees, in enforcing this provision.

To receive indemnification from Company, CHMC must: (i) notify the Company promptly of the assertion of any such claims against it (an "Indemnifiable Claim"); *provided that* any delay by the CHMC in giving notice to Company of an Indemnifiable Claim will not affect the CHMC's right to be indemnified for such Indemnifiable Claim except to the extent that Company is actually prejudiced in its ability to defend against such Indemnifiable Claim; and, (ii) authorize and permit Company to conduct and exercise control of the defense and disposition of such claims, provided however, that Company agrees not to enter into any settlement or compromise of any claim or action in a manner that admits fault or imposes any restrictions or obligations upon an CHMC without that CHMC's prior written consent, which will not be unreasonably withheld.

13.2 Insurance. Company will, beginning with the first clinical trial or the first commercial sale or other commercialization of Products or Processes, whichever occurs earlier, and continuing during the Term, carry workers' compensation insurance in the amounts statutorily required, and occurrence-based liability insurance, including products liability, general commercial liability and contractual liability, in an amount sufficient to cover the liability assumed by Company hereunder, such amount being at least Five Million Dollars $5,000,000 per occurrence and Ten Million Dollars $10,000,000 annual aggregate. Such policy will name CHMC as an additional insured and require at least fifteen (15) days notice to CHMC prior to any cancellation or material change. Company will provide CHMC a certificate evidencing such coverages from time to time upon CHMC's reasonable request. The amounts of insurance coverage required herein will not be construed as creating any limitation on Company's indemnification obligations under this Agreement.

13.3 Exclusion of Damages; Limitation of Liability. NEITHER CHMC NOR ITS AFFILIATES SHALL BE LIABLE TO ANY PARTY FOR SPECIAL, EXEMPLARY, INDIRECT, CONSEQUENTIAL OR PUNITIVE DAMAGES, WHETHER IN CONTRACT, WARRANTY, TORT, STRICT LIABILITY OR OTHERWISE, ARISING OUT OF OR IN CONNECTION WITH THIS AGREEMENT, THE PATENTS, TECHNOLOGY, BIOLOGICAL MATERIALS, PRODUCTS OR PROCESSES, INCLUDING BUT NOT LIMITED TO DAMAGES MEASURING LOST PROFITS, GOODWILL OR BUSINESS OPPORTUNITIES, EVEN IF ADVISED IN ADVANCE OF THE POSSIBILITY OF SUCH DAMAGES.

13.4 Limitation of Liability. IN NO EVENT WILL CHMC'S AND ITS AFFILIATES' TOTAL AND CUMULATIVE LIABILITY TOGETHER OF ANY KIND, EVEN FOR DIRECT DAMAGES, ARISING OUT OF OR IN CONNECTION WITH THIS AGREEMENT, THE PATENTS, TECHNOLOGY, BIOLOGICAL MATERIALS, PRODUCTS AND PROCESSES, EXCEED THE TOTAL AMOUNT OF THE PAYMENTS ACTUALLY RECEIVED BY CHMC.

ARTICLE 14 - NOTICES

14.1 All notices to be given hereunder will be in writing and personally delivered or sent by postage pre-paid first class mail , air mail if not domestic (except that payments and notices of breach or that otherwise materially affect the parties' rights hereunder must be sent postage pre-paid by international certified mail, return receipt requested or international Federal Express or other similar reputable international courier or postal services providing a tracking or return receipt delivery) addressed to the respective parties at the following addresses, or such other address and/or individual as a party will designate in writing for such purpose:

14.2 Notices and other communications to Company concerning this Agreement will be addressed to:

Erin Henderson_____
Chief Business Officer_____
201 E Fiftth Street, Suite 1900_____
Cincinnati, OH 45202_____
ehenderson@bluewatervaccines.com

Invoices related to fees or patent expenses shall be addressed to:

Accounts Payable_____
201 E Fiftth Street, Suite 1900_____
Cincinnati, OH 45202_____
Email: ap@bluewatervaccines.com_____

14.3 Notices and other communications to CHMC concerning this Agreement will be addressed to:

Cincinnati Children's Hospital Medical Center
Legal Department
3333 Burnet Avenue, Mail Location 7032
Cincinnati, Ohio 45229-3039, U.S.A.

Cincinnati Children's Hospital Medical Center
Innovation Ventures
3333 Burnet Avenue, Mail Location 7032
Cincinnati, Ohio 45229-3039, U.S.A.
Fax: 513/636-8453
ATTN: Director Portfolio Management

ARTICLE 15 – MISCELLANEOUS

15.1 Assignment. This is a personal contract between CHMC and Company. CHMC has investigated Company, its officers and has selected Company because of the unique qualifications of its business, reputation, competitive posture, and the character of its officers and principals. Neither this Agreement nor any of the rights or obligations hereunder may be assigned or otherwise transferred in whole or in part by Company, whether by contract, change of control, operation of law or otherwise, without the prior written consent of CHMC, and any attempt to so transfer without such written consent will be void and of no effect. Subject to the foregoing, this Agreement will be binding upon and inure to the benefit of the parties, their legal representatives, heirs and assigns.

15.2 Export Laws. It is understood that CHMC is subject to United States laws and regulations controlling the export of technical data, computer software, laboratory prototypes and other commodities, and that its obligations hereunder are contingent on compliance with all applicable United States export laws and regulations ("Export Laws"). The transfer of certain technical data and/or commodities (which may include the Technology and Biological Materials) may require a license from the cognizant agency of the United States Government and/or written assurances by Company that Company and its Affiliates and Sublicensees will not export data or commodities to certain foreign countries without prior approval of such agency. CHMC neither represents nor warrants that a license will not be required nor that, if required, it will be issued. In any event, Company specifically agrees not to export or re-export any information and/or technical data and/or products in violation of any applicable Government laws and/or regulations. Company agrees to provide notice to and obtain written approval from the CHMC prior to transferring, directly or indirectly, anything enumerated on the Commerce Control List or United States Munitions List. CHMC reserves the right to not accept the item, software, or technology/technical data. Any such decision will not result in breach of contract. Company does not need to provide notice to or obtain written approval from CHMC prior to transferring anything classified as EAR99 or exempt from export control regulations.

15.3 Governing Law; Venue. This Agreement and all matters related thereto will be construed and interpreted under and governed by the laws of the State of Ohio (other than its conflicts of laws provisions) and the federal patent, trademark, copyright and other applicable federal laws of the United States of America, and CHMC and Company hereby submit to the exclusive jurisdiction of the federal and state courts located in Hamilton County, Ohio for the resolution of any dispute, claim or legal proceeding arising out of or related to this Agreement, waive any objection to such jurisdiction on the grounds of venue, forum non conveniens, or similar ground, and agree that any such dispute, claim or proceeding will be brought exclusively in one of those courts.

15.4 Force Majeure. Neither party will be liable for any default or delay in the performance of its obligations under this Agreement to the extent that such default or delay is caused, directly or indirectly, by acts of God, civil disturbance, war, fires, acts or orders of any Government agency or official, other than Company's failure to obtain Regulatory Approvals, natural catastrophes, or any other circumstances beyond such party's reasonable control. In any such event, the non-performing party will be excused from any further performance or observance of the obligation so affected only for as long as such circumstances prevail and such party continues to use commercially reasonable efforts to recommence performance or observance as soon as practicable. Any party whose performance is delayed or prevented by any cause or condition within the purview of this Paragraph will promptly notify the other party thereof, the anticipated duration of the non-performance, and the action(s) being taken to overcome or mitigate the delay or failure to perform**.** Notwithstanding the foregoing, under no circumstances will any delay or nonperformance be excused or forgiven (a) if the cause of the nonperformance could have been prevented or avoided by the exercise of reasonable diligence; (b) if the party whose performance is delayed or prevented fails to use reasonable diligence to promptly overcome and mitigate the delay or failure to perform; or (c) if the nonperformance is caused by the negligence, intentional conduct or misconduct of the nonperforming party. The parties understand and agree that Governmental acts, orders or restrictions do not constitute excusing events hereunder if such acts, orders or restrictions are issued due to either party's alleged failure to conform to applicable laws, regulations or other governmental requirements. If the delay or non-performance lasts for more than 180 days in any 360 day period, then the non-affected party may terminate this Agreement upon written notice with respect to the countries in the Territory affected by the delay or non-performance.

15.5 Severability. The provisions set forth in this Agreement will be considered to be severable and independent of each other. In the event that any provision of this Agreement will be determined to be unenforceable by a court of competent jurisdiction with respect to any country in the Territory, such determination will not be deemed to affect the enforceability of any other provision and the parties agree that any court making such a determination is hereby requested and empowered to modify such provision and to substitute for such unenforceable provision such limitation or provision of a maximum scope as the court then deems reasonable and judicially enforceable and the parties agree that such substitute provision will be as enforceable in said country as if set forth initially in this Agreement. Any such substitute provision will be applicable only in the country in which the original provision was determined to be unenforceable. However, in the event that such court declines to modify such provisions, then the parties will in good faith negotiate a modification to the provision to the minimum extent necessary to render it valid and enforceable in conformity with the parties' intent as manifested herein.

15.6 Headings; Jointly Drafted Agreement. Headings used herein are for reference purposes only and neither limit nor amplify the terms and conditions herein. For purposes of construction, this Agreement will be deemed to have been jointly drafted by the parties and their counsel, and the rule of construction of contracts that ambiguities are construed against the drafting party will not be applied against either party.

15.7 Independent Contractors. The relationship between CHMC and Company created by this Agreement is solely that of independent contractors. This Agreement does not create any agency, distributorship, employee-employer, partnership, joint venture or similar business relationship between the parties. No party is a legal representative of another party, and no party has the right to assume or create any obligation, representation, warranty or guarantee, express or implied, on behalf of another party for any purpose whatsoever. Each party will use its own discretion and will have complete and authoritative control over its employees and the details of performing its obligations under this Agreement.

15.8 Entire Agreement; Amendment. This Agreement, together with its Exhibits, which are hereby incorporated by reference, contains the full understanding of the parties with respect to the subject matter hereof and supersedes all prior understandings and writings relating thereto. It may not be modified or amended except by a writing signed by both parties identified as an amendment to this Agreement.

15.9 Waiver. The waiver by either party of any right, claim, or breach by the other party must be in written form and signed by the party against whom the waiver is charged, and it will not be construed as a waiver of any succeeding right, claim, or breach.

15.10 Counterparts. This Agreement may be executed in separate counterparts, each of which so executed and delivered will constitute an original, but all such counterparts will together constitute one and the same instrument. Any such counterpart may comprise one or more duplicates or duplicate signature pages any of which may be executed by less than all of the parties provided that each party executes at least one such duplicate or duplicate signature page.

IN WITNESS WHEREOF, the parties hereto have caused this Agreement to be executed by their properly and duly authorized officers or representatives as of the Effective Date.

CHILDREN'S HOSPITAL MEDICAL CENTER	***COMPANY***
/s/ Abram S. Gordon	/s/ Joseph Hernandez
Signature	Signature
Abram S. Gordon	
Printed Name	Printed Name
Vice President, Innovation Ventures	
Title	Title

Exhibit A
Company's Affiliates

Exhibit B
Patents

Case 2008-1213:

- U.S. Patent 8,486,421, entitled “Antigen-Norovirus P-Domain Monomers and Dimers, Antigen-Norovirus P-Particle Molecules, and Methods of Their Making and Use”, filed on Jan. 9, 2010, issued on Jul. 16, 2013, with priority dates of Jun. 9, 2009 (Provisional application No. 61/185.564) and Jul. 10, 2009 (provisional application No. 61/224,696)

- U.S. Patent 9,096,644, entitled “Antigen-Norovirus P-Domain Monomers and Dimers, Antigen-Norovirus P-Particle Molecules, and Methods of Their Making and Use”, filed on Jun. 9, 2009, with a priority date of Jul. 10, 2009.

- European Patent 2440582, entitled “Antigen-Norovirus P-Domain Monomers and Dimers, Antigen-Norovirus P-Particle Molecules, and Methods of Their Making and Use”, filed on Jun. 9, 2010, issued on Nov. 7, 2018, with priority dates of Jun 9, 2009 (Provisional application No. 61/185.564) and Jul. 10, 2009 (provisional application No. 61/224,696) (validated in France, Germany, Italy, UK)

- Japan Patent 5894528, entitled “Antigen-Norovirus P-Domain Monomers and Dimers, Antigen-Norovirus P-Particle Molecules, and Methods of Their Making and Use”, filed on Jun. 9, 2010, issued on Mar. 4, 2016, with priority dates of Jun 9, 2009 (Provisional application No. 61/185.564) and Jul. 10, 2009 (provisional application No. 61/224,696)

Case 2017-0103:

- U.S. Patent Application No. 16/489,095, entitled “Norovirus S Particle Based Vaccines and Methods of Making and Using Same,” filed on Aug. 27, 2019, with priority date Mar. 28, 2017 (Provisional Application No. 62/477,481)

- Euopean Patent Application No. 18777340.3, entitled “Norovirus S Particle Based Vaccines and Methods of Making and Using Same,” filed on Sept. 12, 2019, with priority date Mar. 28, 2017 (Provisional Application No. 62/477,481)

- Japan Patent Application No. 2019-546799, entitled “Norovirus S Particle Based Vaccines and Methods of Making and Using Same,” filed on Aug. 27, 2019, with priority date Mar. 28, 2017 (Provisional Application No. 62/477,481)

- China Patent Application No. 201880017019.3, entitled “Norovirus S Particle Based Vaccines and Methods of Making and Using Same,” filed on Sept. 9, 2019, with priority date Mar. 28, 2017 (Provisional Application No. 62/477,481)

- Hong Kong Patent Application No. 62020005692.2, entitled “Norovirus S Particle Based Vaccines and Methods of Making and Using Same,” filed on April 13, 2020, with priority date Mar. 28, 2017 (Provisional Application No. 62/477,481)

Case 2020-1205

- U.S. Provisional Patent Application No. 63/149,742, filed on Feb. 16, 2021, and U.S. Provisional Patent Application No. 63/162,369, filed on Mar. 17, 2021, both entitled “S60-HA1 pseudovirus nanoparticles as a new influenza vaccine tactic and candidate”.

Case 2012-0113

- US Patent No 9,562,077, entitled “Protein Complex System for Increased Immunogenicity and Functionality, and Methods Making and Use”, filed on Mar. 14, 2013, with priority date July 11, 2012 (Provisional Application No. 61/670,288).

Exhibit C
Development and Commercialization Plan

Exhibit 10.9

Certain portions of this exhibit have been omitted pursuant to Rule 601(b)(10) of Regulation S-K The omitted information is (i) not material and (ii) would likely cause competitive harm to Blue Water Vaccines, Inc. if publicly disclosed. Information that has been omitted has been noted in this document with a placeholder identified by the mark "[***]".

DATED
16th July 2019

(1) OXFORD UNIVERSITY INNOVATION LIMITED

and

(2) BLUE WATER VACCINES INC.

LICENCE OF TECHNOLOGY
(OUI PROJECT Nos. 13709, 16867, 16870 and 16872)

THIS AGREEMENT is made on

BETWEEN:

(1) OXFORD UNIVERSITY INNOVATION LIMITED (Company No. 2199542) whose registered office is at University Offices, Wellington Square, Oxford OXl 2JD, England ("QUI"); and

(2) BLUE WATER VACCINES INCORPORATED (Company Registration No.) whose registered office is at 1013 Centre Rd, Suite 403-B New Castle Wilmington Delaware 19805 USA (the "Licensee").

BACKGROUND:

The Licensed Technology is connected with QUI Project Numbers: 13709, 16867, 16870 and 16872 which comprise components from the Haemagglutinin proteins of Influenza A Group 1, Influenza Group 2 and Influenza B and a VLP delivery system which together form a candidate Universal Influenza vaccine. The Licensee wishes to acquire a licence to the Licensed Technology and QUI is willing to license the Licensed Technology to the Licensee, on the terms of this agreement.

AGREEMENT:

1. Interpretation

In this agreement (including its Schedules), any reference to a "clause" or "Schedule" is a reference to a clause of this agreement or a schedule to this agreement, as the case may be. Words and expressions used in this agreement have the meaning set out in Schedule 1.

2. Condition Precedent

2.1 The Licence and all obligations of the parties under this agreement (other than the obligations set out in Clause) are conditional upon the Licensee entering into an agreement with the University to provide funding for 3 years' salary for Dr Craig Thompson in the University's Department of Zoology (minimum of £420,000 to be pre-paid to the University in advance or placed in escrow) to be paid by 31st December 2019

2.2 If this condition has not been satisfied or waived on or before 5 p.m. on 31st December 2019 (or such later time and date as is agreed by QUI), this agreement shall be rendered null and void; except that the parties agree that confidentiality provisions in clause 8 will continue in full force and effect in accordance with 12.8 all of the obligations of the parties under this agreement shall cease and no party shall have any licence, right or claim against any other party under this agreement.

3. Grant of Licence

3.1 In consideration of the payments required to be made under this agreement by the Licensee QUI grants to the Licensee a licence in the Territory in respect of the Licensed Technology in the Field to develop, make, have made, use and have used and Market the Licensed Product on and subject to the terms and conditions of this agreement. Subject to clause 5, the Licence is exclusive in the Field in relation to the Licensed Intellectual Property Rights. The Licence is non exclusive in relation to the Licensed Kno w-How. QUI retains unrestricted rights to use and license others to use the Licensed Know-How, and to use and license the Licensed Technology outside the Field.

3.2 As soon as is reasonably possible after the date of this agreement, OUI will, at QUl's cost, supply the Licensee with the Documents.

3.3 The Licensee may grant sub-licences with the prior written consent of QUI, such consent not to be unreasonably withheld, provided that:

(a) the sub-licensee has obligations to the Licensee commensurate with those which the Licensee has to QUI under this agreement, except where it is not legally possible to include such obligations in the sub-licence; and

(bl the nature of the proposed sub-licensee is not likely in OUl's opinion to have any detrimental impact on the reputation of either QUI or of the University; and

(cl immediately following the grant of each sub-licence, the Licensee provides a certified copy of that sub-licence to OUI; and

(d) no sub-licence will carry any right to sub-sub-license.

4. Additional Applications and Improvements

4.1 The Applications will include the Additional Applications once those projects have been assigned by the University to OUI and all references to the Applications throughout the agreement will include the Additional Applications.

4.2 The Licensed Technology covered by the Licence in clause 2 includes Inventor Improvements. QUI will communicate in writing to the Licensee within a reasonable time all Inventor Improvements.

4.3 The Licensee acknowledges and agrees that all Intellectual Property Rights in Inventor Improvements belong to QUI.

4.4 The Licensee will communicate in writing to QUI within a reasonable time all Licensee Improvements.

4.5 QUI acknowledges and agrees that all Intellectual Property Rights in the Licensee Improvements belong to the Licensee.

5. Rights Re Non-Commercial Use

5.1 The Licensee grants QUI an irrevocable, perpetual, royalty-free licence to grant the University and those persons who at any time work or have worked on the Licensed Technology the licence set out in clause 5.2.

5.2 QUI has granted and, in respect of Licensee Improvements, will grant, to the University and those persons who at any time work or have worked on the Licensed Technology a non transferable, irrevocable, perpetual, royalty-free licence to use and publish the Licensed Technology and the Licensee Improvements for Non-Commercial Use.

6. Filing and Maintenance

6.1 The Licensee will pay OUI the Past Patent Costs representing the Licensee's sole contribution to the patent costs incurred by OUI prior to the parties entering into this agreement, within thirty (30) days of receiving an invoice from OUI.

6.2 QUI will, in consultation with the Licensee and at the Licensee's cost, prosecute, use all reasonable endeavours to maintain, and renew the Applications throughout the duration of this Licence Agreement. The Licensee will reimburse OUI for all costs, filing fees, lawyers' and patent agents' fees, expenses and outgoings of whatever nature incurred by OUI in the prosecution, maintenance and renewal of the Applications (including those incurred in opposition proceedings before the European Patent Office or in ex parte re-examination or inter partes review proceedings in the United States Patent and Trademark Office ("USPTO") or any similar proceedings before any patent office challenging the grant or validity of the Applications) within thirty (30) days of receiving an invoice from OUI. OUI shall be entitled to make it a condition of any action of OUI under this clause 6.2 that the Licensee provides QUI with sufficient money in advance to cover the costs likely to be incurred in the action.

6.3 Where the Applications are prosecuted in the USPTO and the Licensee is a small business concern as defined under the US Small Business Act (15USC632) QUI intends to pay reduced USPTO patent fees under US patent law 3SUSC 41(h)(l). The Licensee will notify OUI as soon as reasonably possible if it or a sub-licensee ceases to be a small business concern as defined under the US Small Business Act (1SUSC632) or becomes aware of any other reason why it would not qualify for reduced USPTO patent fees under US patent law 35USC 41(h)(l).

6.4 The Licensee shall inform QUI not less than six (6) months in advance of the National Phase filing deadline (noted in Schedule 2) of the territories within the scope of the PCT that it wishes to be covered in the National Phase of that Application. In the event that the Licensee does not give the required minimum of six months advance notice QUI shall then be entitled to proceed with filing the Applications at the licensee's cost in whichever territories as it may in its sole discretion decide.

6.5 The Licensee shall be entitled to remove any one or more of the countries from the Territory at any time by giving not less than six months notice to OUI. If an Application is proceeding under the PCT then such notice may not be given any earlier than the date for commencement of the National Phase filing. For the avoidance of doubt the Licensee shall remain liable for the costs mentioned in clause 6.2 that arise or are incurred by OUI during the said notice period in respect of the countries being removed.

7. Infringement

7.1 Each party will notify the other in writing of any misappropriation or infringement of any rights in the licensed Technology of which the party becomes aware.

7.2 The licensee has the first right (but is not obliged) to take Legal Action at its own cost in relation to any misappropriation or infringement of any rights included in the Licensed Intellectual Property Rights in the Field. The Licensee must discuss any proposed Legal Action with OUI prior to the Legal Action being commenced, and take due account of the legitimate interests of OUI in the Legal Action it takes.

7.3 If the Licensee takes Legal Action under clause 7.2, the Licensee will:

7.3.1 indemnify and hold OUI and the University harmless against all costs (including lawyers' and patent agents' fees and expenses), claims, demands and liabilities arising out of or consequent upon a Legal Action and will settle any invoice received from QUI in respect of such costs, claims, demands and liabilities within thirty (30) days of receipt; and

7.3.2 treat any account of profits or damages (including, without limitation, punitive damages) awarded in or paid to the Licensee under any settlement ofthe Legal Action as Net Sales for the purposes of clause 8, having first for these purposes deducted from the award or settlement an amount equal to any legal costs incurred by the Licensee in the Legal Action that are not covered by an award of legal costs; and

7.3.3 keep QUI regularly informed of the progress of the Legal Action, including, without limitation, any claims affecting the scope of the Licensed Technology.

7.4 QUI may take any Legal Action at its own cost in relation to any misappropriation or infringement of any rights included in the Licensed Intellectual Property Rights where:

7.4.1 the Licensee has notified QUI in writing that it does not intend to take any Legal Action in relation to any misappropriation or infringement of any such rights; or

7.4.2 if having received professional advice with regard to any Legal Action within fourteen (14) days of the notification under clause 7.1, and consulted with QUI, the Licensee does not take reasonable steps to act upon an agreed process for dealing with such misappropriation or infringement (which may include, for the avoidance of doubt, seeking a second opinion in respect of such professional advice) within any timescale agreed between OUI and the Licensee and in any event within forty-five (45) days of notification under clause 7.1, provided it shall not settle any action without first consulting with the Licensee and taking account of the reasonable observations and requests of the Licensee.

7.5 Subject to clauses 7.2 and 7.3, if the Licensee takes Legal Action QUI will provide such reasonable assistance as requested by the Licensee in relation to such Legal Action at the Licensee's cost, provided that the Licensee indemnifies QUI under clause 7.3 for the costs of any legal representation in the Legal Action required by QUI.

8. Confidentiality

8.1 Subject to clauses 8.2, Error! Reference source not found. and 8.4, each party (being a receiving or disclosing party as the case may be) will keep confidential the Confidential Information of the other party and will not disclose or supply the Confidential Information to any third party or use it for any purpose, except in accordance with the terms and objectives of this agreement.

8.2 The Licensee may disclose to sub-licensees of the Licensed Technology such of the Confidential Information of which it consists as is necessary for the exercise of any rights sub-licensed, provided that the Licensee shall ensure that such sub-licensees accept a continuing obligation of confidentiality in the same terms as this clause, and giving third party enforcement rights to OUI, before the Licensee makes any disclosure ofthe Confidential Information.

8.3 Confidential Information may be exchanged freely between QUI and the University and communications between those two parties shall not be regarded as disclosures, dissemination or publication for the purpose of this agreement. QUI may also disclose the terms of this agreement and royalty reports and payments made by the Licensee to any third parties that have rights to a revenue share for providing funding in the development of the Licensed Technology.

8.4 Clause 8.1 will not apply to any Confidential Information which:

8.4.1 is known to the receiving party before disclosure, and not subject to any obligation of confidentiality owed to the disclosing party;

8.4.2 is or becomes publicly known without the fault ofthe receiving party;

8.4.3 is obtained by the receiving party from a third party in circumstances where the receiving party has no reason to believe that it is subject to an obligation of confidentiality owed to the disclosing party;

8.4.4 the receiving party can establish by reasonable proof was substantially and independently developed by officers or employees of the receiving party who had no knowledge of the disclosing party's Confidential Information; or

8.4.5 is approved for release in writing by an authorised representative of the disclosing party.

8.5 Nothing in this agreement will prevent a party from disclosing Confidential Information where it is required to do so by law or regulation or by order of a court or competent authority, provided that, in the case of a disclosure under the Freedom of Information Act 2000 ("FOIA"), none of the exemptions in the FOIA applies to the relevant Confidential Information.

8.6 If either party to this agreement receives a request under the FOIA to disclose any information that, under this agreement, is the other party's Confidential Information, it will notify and consult with the other party. The other party will respond within five (5) days after receiving notice if that notice requests the other party to provide information to assist in determining whether or not an exemption under the FOIA applies to the information requested under the FOIA.

9. Royalties and Other Payments

9.1 OUI will invoice the Licensee for the Signing Fee shortly after signature of this agreement and the Licensee must settle the invoice within thirty (30) days of receipt.

9.2 The Licensee will pay to OUI a royalty equal to the Royalty Rate on all Net Sales of Licensed Products. The Licensee will also pay to OUI a royalty equal to the Royalty Rate on any sums received from a sub-licensee to meet an obligation under the terms of a sub-licence to pay a minimum sum over and above the actual royalties due to be paid by that sub-licensee on sales of Licensed Products.

9.3 Following expiration or revocation of the last Valid Claim covering a Licensed Product is Marketed the Step Down Royalty Rate shall apply to such Licensed Products.

9.4 In the event that the royalties paid to OUI under clause 9.2 do not amount to at least the Minimum Sum, the Licensee must make up the difference between the royalties paid under clause 9.2 and the Minimum Sum in each Licence Year where a Minimum Sum applies.

9.5 The Licensee will pay to OUI a royalty equal to the Fee Income Royalty Rate on all up-front, milestone and other one-off payments (other than payments made solely in relation to research provided by the Licensee) received by the Licensee under or in connection with all sub-licences and other contracts granted by the Licensee with respect to the Licensed Technology. The Licensee will pay each such royalty within thirty (30) days after its receipt of the payment to which the royalty relates.

9.6 The licensee will notify QUI as soon as possible after it or any sub-licensee achieves any Milestone, and pay to OUI the Milestone Fee in respect of each Milestone within thirty (30) days of the date on which each Milestone is achieved by the Licensee or a sub-licensee.

9.7 The Signing Fee and the Milestone Fee are non-refundable and will not be considered as an advance payment on royalties payable under clause 9.2. No part of the Minimum Sum will be refundable or applicable to succeeding Licence Years.

9.8 The Minimum Sum and the Milestone Fee will be indexed to the RPI and each Minimum Sum and Milestone will be increased (or decreased, if appropriate) by the percentage change in the RPI between the date of this agreement and:

(a) in the case of any Minimum Sum, the last day of the Licence Vear to which it relates; and

(b) in the case of any Milestone Fee, the date on which the Milestone to which it relates is achieved.

9.9 The licensee may supply a commercially reasonable quantity of licensed Products for promotional sampling provided that the number of Licensed Products supplied for promotional sampling shall not be greater than 5% of total number of units of each Licensed Product sold leased or licensed by the Licensee in any Quart er. Except as set out in this clause, the Licensee must not accept or solicit any non-monetary consideration when Marketing Licensed Products or when issuing sub-licences of the Licensed Technology without the prior written consent of QUI.

9.10 The licensee will make all payments in pounds sterling or any currency replacing pounds sterling in its entirety.

9.11 For the purposes of calculating any amount payable by the Licensee to OUI in a currency other than pounds sterling (or replacement currency), the Licensee shall apply an exchange rate equivalent to the average of the applicable closing mid rates quoted by the Financial Times as published in London on:

(a) the first Business Day of each month during the quarter just closed; or

(b) for payments under clause 9.5 only, the first Business Day of the month in which the payment was received by the Licensee.

9.12 Where the Licensee has to withhold tax by law, the Licensee will deduct the tax, pay it to the relevant taxing authority, and supply OUI with a Certificate of Tax Deduction at the time of payment to OUI.

9.13 In the event that full payment of any amount due from the Licensee to OUI under this agreement is not made by any of the dates stipulated, the Licensee shall be liable to pay interest on the amount unpaid at the rate of eight per cent (8%) per annum over the base rate for the time being of Barclays Bank pie. Such interest shall accrue on a daily basis from the date when payment was due until the date of actual payment of the overdue amount, whether before or after judgment, and shall be compounded quarterly.

9.14 If the Licensed Product is of a description covered by the Medicines Access Policy, the Licensee shall adhere to the requirements ofthe Medicines Access Polic y.

10. Best Endeavours

10.1 The Licensee must use its best endeavours to develop, exploit and Market the Licensed Technology to maximise the financial return for both parties.

10.2 The Licensee must use its best endeavours to develop, exploit and Market the Licensed Technology in accordance with the Development Plan .

11. Royalty Reports and Audit

11.1 The Licensee will provide OUI with a report at least once in every six (6) months detailing the activities and achievements in its development of the Licensed Technology in order to facilitate its commercial exploitation, and in the development of potential Licensed Pro ducts.

11. 2 The Licensee will provide OUI with a royalty report within thirty (30) days after the close of each Quarter for each Licensed Product Marketed by the Licensee and its sub-licensees. Each Royalty Report will:

(al set out the Net Sales of each Licensed Product Marketed by the Licensee and any sub licensees, including the total gross selling price of each Licensed Product Marketed by the Licensee and any sub-licensees and the quantity or total number of units of each Licensed Product Marketed by the Licensee and any sub-licensees;
(b) set out details of deductions made in the calculation of Net Sales from the invoiced price of each Licensed Product in the form in which it is Marketed by the Licensee or any sub licensees;
(c) set out details of the quantity of Licensed Products used for promotional sampling by the Licensee or any sub-licensees;
(d) set out details of any deductions made under clause 10.4 below;
(el provide a calculation of the royalties due;
(f) set out details of payments received by the Licensee to which the Fee Income Royalty Rate applies and provide a calculation of the royalties due;
(g) provide a statement showing whether or not royalties due exceed the Minimum Sum and, if so, by how much;
(h) set out details of Milestones achieved by the Licensee or any sub-licensees; and
(i) set out the steps taken during the Licence Year to promote and Market Licensed Produ cts.

The Licensee must pay OUI the royalties due in respect of the Quarter just closed at the same time as the Licensee delivers the Royalty Report.

11.3 The Licensee will deliver to OUI a periodic report at the close of each Licence Year providing sufficient data (in outline form) to give a reasonable indication or estimate of the actual or expected market share of the Licensee and its sub-licensees and will notify OUI in the event that its market share does or is expected to breach the limits set out in the 2014 Commission Regulation 316/2014 Technology Transfer Block Exemption Regulation and Guidelines in Commission Communication 2014/c 89/03 and any successor regulation. This obligation is not intended to place a significant additional financial burden on the Licensee.

11.4 If the Licensee has to pay royalties to a third party (other than an Affiliate), for the right to use a proprietary manufacturing process or proprietary adjuvants in order to make or have made a Licensed Product, under a licence of Intellectual Property Rights without which the Licensed Technology cannot be lawfully exploited, then the Licensee will be entitled to deduct from all payments due to OUI at the Royalty Rate on Net Sales of Licensed Products in respect of the products concerned an amount equal to fifty per cent (50%) of the royalties actually paid to that third party, up to a maximum amount of twenty-five percent (25%) of the royalties due to OUI.

11.5 If a Licensed Product Marketed by the Licensee is re-Marketed by an Affiliate or an entity over which the Licensee exercises Control, the royalty on each such Licensed Product will be calculated on the highest of the prices at which it is Marketed or re-Marketed.

11.6 The Licensee must keep complete and proper records and accurate accounts of all Licensed Products used and Marketed by the Licensee and any sub-licensee in each Licence Year for at least six (6) years. OUI may, through an independent certified accountant appointed by OUI ("the Auditor"), audit all such accounts on at least thirty (30) days' written notice no more than once each Licence Year for the purpose of determining the accuracy of the Royalty Reports and payments. The Auditor shall be:

11.6.1 permitted by the Licensee to enter the Licensee's principal place of business upon reasonable notice to inspect such records and accounts;

11.6.2 entitled to take copies of or extracts from such records and accounts;

11.6.3 given all other information by the Licensee as may be necessary or appropriate to enable the amount of royalties payable to be ascertained including the provision of relevant records; and

11.6.4 shall be allowed access to and permitted to conduct interviews of any sales, engineering or other staff of the Licensee in order to verify the accuracy of the records and accounts and the accuracy of any statements provided to OUI under clause 11.2.

If on any such audit a shortfall in payments of greater than two percent (2%) is discovered by the Auditor in respect of the audit period, the Licensee shall pay OUl's audit costs.

11.6 ●The auditing rights and obligations on the Licensee set out in clause 11.6 will apply equally to any sublicenses allowed for in this agreement and the Licensee will ensure that the same obligations and access rights allowing OUI auditing rights to the sub-licensee are included in each sub licence agreement.

12. Duration and Termination

12.1 Subject to clause 2, this agreement will take effect on the date of signature. Subject to the possibility of earlier termination under the following provisions of this clause 12, and subject to the possibility of an extension to the term by mutual agreement, this agreement shall continue in force until the expiry of ten years following the last to expire of all patents and patent applications within the definition of the Application.

12.2 If either party commits a material breach of this agreement, and the breach is not remediable or (being remediable) is not remedied within the period allowed by notice given by the other party in writing calling on the party in breach to effect such remedy (such period being not less than thirty (30) days), the other party may terminate this agreement by written notice having immediate effect.

12.3 The Licensee may terminate this agreement for any reason at any time provided it gives QUI six (6) months' written notice to terminate expiring after the third anniversary of this agreement whereupon the Licensee shall bring all sub-licences to an end on the same date. Any such termination shall not absolve the Licensee of its obligation to accrue and pay royalties and other payments under the provisions of clause 9 in respect of the period prior to termination.

12.4 QUI may terminate this agreement:

(a) immediately, if the Licensee has a petition presented for its winding-up, or passes a resolution for voluntary winding-up otherwise than for the purposes of a bona fide amalgamation or reconstruction, or compounds with its creditors, or has a receiver administrator or administrative receiver appointed of all or any part of its assets, or enters into any arrangements with creditors, or takes or suffers any similar action in consequence of debts;

(b) on thirty (30) days' written notice if:
  (i) the Licensee opposes or challenges the validity of the Application or raises the claim that the Know-How is not necessary to develop and Market Licensed Products; or
  (ii) in OUl's reasonable opinion, the Licensee is taking insufficient or inadequate steps to develop or Market the Licensed Products and the Licensee does not take any further steps requested by QUI by written notice within a reasonable time.

12.5 On termination or expiration of this agreement, for whatever reason, the Licensee:

(a) must bring all sub-licences to an end on the same date;
(b) shall pay to OUI all outstanding royalties and other sums due under this agreement;
(c) shall provide OUI with details of the stocks of Licensed Products held at the point of termination;
(d) must cease to use or exploit the Licensed Technology, provided that this restriction does not apply to Licensed Know-How which has entered the public domain through no fault of the Licensee, and that the Licensee may continue to use the Licensed Technology in order to meet any specific existing binding commitments already made by the Licensee at the date of termination and requiring delivery of Licensed Products within the next six (6) months;
(e) must, at the option of QUI and at the Licensee's cost, destroy all other Licensed Products or send all other Licensed Products to a location nominated by OUI to the Licensee in writing; and
(f) grants OUI an irrevocable, transferable, non-exclusive licence to develop, make, have made, use and Market the Licensee's Improvements and products that incorporate, embody or otherwise exploit the same. OUI shall pay a reasonable royalty for use of this licence unless the termination arises under clause 12.4, or is by QUI under clause 12.2, in which case it shall be royalty-free.

12.6 Termination of this agreement, whether for breach of this agreement or otherwise, shall not absolve the Licensee of its obligation to accrue and pay royalties under the provisions of clause 8 for the duration of any notice period and in respect of any dealings in Licensed Products permitted by clause 12.5 or to reimburse OUI for all costs, filing fees, lawyers' and patent agents' fees, expenses and outgoings of whatever nature incurred by OUI in the prosecution, maintenance and renewal of the Application duration of any notice period in accordance with clause 6.2.

12.7 Clauses 1, 5.2, 7.3, 12.5, 12.7, 12.8, 13, 14.4 and 14.14 will survive the termination or expiration of this agreement, for whatever reason, indefinitely.

12.8 Clauses 8 and 11.6 will survive the termination or expiration of this agreement, for whatever reason, for a period of six (6) years.

13. Liability

13.1 To the fullest extent permissible by law, OUI does not make any warranties of any kind including, without limitation, warranties with respect to:
(a) the quality of the Licensed Technology;
(bl the suitability of the Licensed Technology for any particular use;
(cl whether use of the Licensed Technology will infringe third-party rights; or
(dl whether the Applications will be granted or the validity of any patent that issues in response to those Applications.

13.2 The Licensee agrees to indemnify OUI and the University and hold OUI and the University harmless from and against any and all claims, damages and liabilities:
(a) asserted by third parties (including claims for negligence) which arise directly or indirectly from the use of the Licensed Technology or the Marketing of Licensed Products by the Licensee and/or its sub-licensees; and/or
(bl arising directly or indirectly from any breach by the Licensee of this agreement.

13.3 OUI will use reasonable endeavours to defend any Indemnified Claim or (at OUl's option) allow the Licensee to do so on its behalf (subject to the University retaining the right to be kept informed of progress in the action and to have reasonable input into its conduct.) QUI will not (except as required by law) make any admission, compromise, settlement or discharge of any Indemnified Claim without the consent of the Licensee (which will not be unreasonably withheld or delayed).

13.4 The Licensee undertakes to make no claim against any employee, student, agent or appointee of OUI or of the University, being a claim which seeks to enforce against any of them any liability whatsoever in connection with this agreement or its subject-matter.

13.5 Subject to clause 13.7 and except in relation to the indemnities in clause 7.3 and 13.2, the liability of either party for any breach of this agreement, in negligence or arising in any other way out of the subject-matter of this agreement, will not extend to incidental or consequential damages or to any loss of profits.

13.6 Subject to clause 13.7, the liability of OUI to the Licensee accruing in any Licence Year under or otherwise in connection with this agreement or its subject-matter, including without limitation liability for negligence, shall in no event exceed:

(al in respect of liability accruing in the first Licence Year, the amount of the Signing Fee paid to OUI; and

(bl in respect of liability accruing in any subsequent Licence Year, the total royalties paid in the previous Licence Year to OUI under clause 9.2.

13.7 Nothing in this agreement shall limit or exclude any liability for fraud or fraudulent misrepresentation or death, or personal injury or any other liability which may not, by law, be excluded.

14. General

14.1 Registration - The licensee must register its interest in the Licensed Technology with any relevant authorities in the Territory as soon as legally possible. The Licensee must not, however, register an entire copy of this agreement in any part of the Territory or disclose its financial terms without the prior written consent of OUI.

14.2 Advertising - The Licensee must not use the name of OUI, the University or the Inventors in any advertising, promotional or sales literature, without OUl's prior written approval.

14.3 Packaging - The Licensee will ensure that the Licensed Products and the packaging associated with them are marked suitably with any relevant patent or patent application numbers to satisfy the laws of each of the countries in which the Licensed Products are sold or supplied and in which they are covered by the claims of any patent or patent application, to the intent that CUI shall not suffer any loss or any loss of damages in an infringement action.

14.4 Thesis - This agreement shall not prevent or hinder registered students of the University from submitting for degrees of the University theses based on the Licensed Technology; or from following the University's procedures for examinations and for admission to postgraduate degree status.

14.5 Taxes - Where the licensee has to make a payment to OUI under this agreement which attracts value-added, sales, use, excise or other similar taxes or duties, the Licensee will be responsible for paying those taxes and duties.

14.6 Notices - All notices to be sent to CUI under this agreement must indicate the CUI Project N!:! and should be sent, by post and fax unless agreed otherwise in writing, until further notice to: The Managing Director, Oxford University Innovation Ltd, Buxton Court, 3 West Way, Oxford OX2 OJB, Fax: +44 (0)1865 280831. All notices to be sent to the Licensee under this agreement should be sent, until further notice, to the Licensee's Contact and Address indicating the OUI Project N!!.

14.7 Force Majeure - If performance by either party of any of its obligations under this agreement (not including an obligation to make payment) is prevented by circumstances beyond its reasonable control, that party will be excused from performance of that obligation for the duration of the relevant event.

14.8 Assignment - The Licensee may not assign any of its rights or obligations under this agreement in whole or in part, except to an Affiliate and only for so long as it remains an Affiliate, without the prior written consent of QUI. Assignment, for these purposes, includes the acquisition of Control of the Licensee by a third party. If QUI assigns its rights in the Licensed Technology to any person it shall do so expressly subject to the licensee's rights under this Agreement.

14.9 Severability - If any of the provisions of this agreement is or becomes invalid, illegal or unenforceable, the validity, legality or enforceability of the remaining provisions will not in any way be affected or impaired. The parties will, however, negotiate to agree the terms of a mutually satisfactory provision, achieving as nearly as possible the same commercial effect, to be substituted for the provision found to be void or unenforceable.

14.10 No Partnership etc - Nothing in this agreement creates, implies or evidences any partnership or joint venture between QUI and the Licensee or the relationship between them of principal and agent.

14.11 Entire Agreement - This agreement constitutes the entire agreement between the parties in relation to the Licence to the exclusion of all other terms and conditions (including any terms or conditions which the licensee purports to apply under any purchase order, confirmation order, specification or other document). The Licensee has not relied on any other statements or representations in agreeing to enter this agreement and waives all claims for breach of any warranty and all claims for any misrepresentation, (negligent or of any other kind, unless made by QUI fraudulently) in relation to any representation which is not specifically set out in this agreement. Specifically, but without limitation, this agreement does not impose or imply any obligation on QUI or the University to conduct development work. Any arrangements for such work must be the subject of a separate agreement between the University and the Licensee.

14.12 Variation - Any variation of this agreement must be in writing and signed by authorised signatories for both parties. For the avoidance of doubt, the parties to this agreement may rescind or vary this agreement without the consent of any party that has the benefit of clause 14.14.

14.13 Waiver - No failure or delay by either party in enforcing its rights under this agreement, or at law or in equity will prejudice or restrict those rights. No waiver of any right will operate as a waiver of any other or later right or breach. Except as stated to the contrary in this agreement, no right, power or remedy conferred on, or reserved to, either party is exclusive of any other right, power or remedy available to it, and each of those rights, powers, and remedies is cumulative.

14.14 Rights Of Third Parties - The parties to this agreement intend that by virtue of the Contracts (Rights of Third Parties) Act 1999 the University and the people referred to in clause 13.4 will be able to enforce the terms of this agreement intended by the parties to be for their benefit as if the University and the people referred to in clause 13.4 were party to this agreement.

14.15 Governing Law - This agreement is governed by English Law, and the parties submit to the exclusive jurisdiction of the English Courts for the resolution of any dispute which may arise out of or in connection with this agreement except in relation to any action in relation to Intellectual Property Rights or Confidential Information which may be sought in any court of competent jurisdiction.

Schedule 1

DEFINITIONS
(Clause 1}

Academic and Research Purposes means research, teaching or other scholarly use which is undertaken for the purposes of education and research.

Affiliate means any company or legal entity in any country Controlling or Controlled by the Licensee.

Applications means:

(a) the patent applications set out in Schedule 2 and any further applications notified by OUI to the Licensee that are filed by OUI for covering Influenza A Group 2 and Influenza B that name any of the Inventors as inventors in the application;
(bl any patents granted in response to those applications;
(c) any corresponding foreign patents and applications which may be granted to OUI in the Territory based on and deriving priority from that application; and
(d) any addition, continuation, continuation-in-part, division, reissue, renewal or extension based on the Applications.

Business Day means a day, other than a Saturday or Sunday, on which clearing banks are permitted to open in London.

Clinical Patient Care means diagnosing, treating and/or managing the health of persons under the care of an individual having the right to use the Licensed Technology in the event that such Licensed Technology is capable of application in a healthcare setting without further development.

Confidential Information means in relation to each party any materials, trade secrets or other information disclosed by that party to the other, including, without limitation:

(a) the Licensed Technology, to the extent that it is not disclosed by the Application when published; and
(b) this agreement.

Control means:

(a) ownership of more than fifty percent (50%) of the voting share capital of the relevant entity; or
(b) the ability to direct the casting of more than fifty percent (50%) of the votes exercisable at a general meeting of the relevant entity on all, or substantially all, matters.

Development Plan means the plan set out in Schedule 3.

Documents means the documents and materials set out in Schedule 2. Fee Income Royalty Rate means the royalty rate set out in Schedule 2. Field means the field set out in Schedule 2.

Improvement means any development of the Licensed Technology which would, if commercially practised, infringe and/or be covered by a claim subsisting or being prosecuted in the Application.

Indemnified Claim means any claim under which OUI and the University are entitled to be indemnified under clause 13.2.

Intellectual Property Rights means patents, trade marks, copyrights, database rights, rights in designs, and all or any other intellectual or industrial property rights, whether or not registered or capable of registration.

Inventor means the inventor or inventors named in the Application and identified in Schedule 2.

Inventor Improvements means any Improvements made prior to the second anniversary of the date of this agreement solely by the Inventor within the Field, and the Intellectual Property Rights pertaining to them, of which OUI has been made aware and is legally able to license.

Legal Action means commencing or defending any proceedings before a court or tribunal in any jurisdiction in relation to any rights included in the Licensed Intellectual Property including all claims and counterclaims for infringement and for declarations of non-infringement or invalidity.

Licence means the licence granted by OUI to the Licensee under clause 3.1.

Licensed Intellectual Property Rights means the Application and (to the extent they constitute Intellectual Property Rights) OUl's Improvements.

Licensed Know-how means all confidential information relating to the Application that has been communicated to the Licensee by OUI in writing before the date of this agreement or is communicated in writing to the Licensee by OUI under this agreement and within twelve (12) months after the date of this agreement and (to the extent they constitute confidential information) Inventor Improvements.

Licensed Product means any product, process, service or composition which is entirely or partially produced by means of or with the use of, or within the scope of, the Licensed Technology, or any of it.

Licensed Technology means the Licensed Intellectual Property Rights and the Licensed Know-How, and such (if any) other Intellectual Property Rights owned by or licensed to OUI as may be specifically identified in Schedule 2 (to the extent, in the case of licensed rights, that OUI is legally able to grant a sub-licence of the same).

Licensee's Contact and Address means the address for the Licensee set out in Schedule 2 of this agreement.

Licensee Improvements means any Improvements made prior to the second anniversary of the date of this agreement by the Licensee, and the Intellectual Property Rights pertaining to them.

Licence Year means each twelve {12) month period beginning on the date of this agreement and each anniversary of the date of this agreement.

Market means, in relation to a Licensed Product, offering to sell, lease, licence or otherwise commercially exploit the Licensed Product or the sale, lease, licence or other commercial exploitation of the Licensed Product.

Medicines Access Policy means the policy of the University to promote access to pharmaceutical and other products and services, the current version of which is available at htt ps:// researchsu pport.admin.ox.ac.uk/ policv/ oxford/ medicines.

Milestone and Milestone Fee means the milestones, and the amounts payable on achievement of each of the milestones, set out in Schedule 2.

Minimum Sum means the minimum sum or sums set out in Schedule 2.

Net Sales means the gross selling price of the licensed Product in the form in which it is Marketed by the licensee or any sub-licensee, less:

(a) trade, quantity or cash discounts actually given; and
(b) outbound carriage and packaging expenses actually paid; and
(c) customs duties, sales taxes or other taxes imposed upon and paid with respect to such sales (excluding personal taxes).

Non-Commercial Use means Academic and Research Purposes and the purposes of Clinical Patient Care. This includes the right for the University to license the Licensed Technology to any of its collaborators in connection with and solely for the University's Academic and Research Purposes; but it does not include the right to grant any license to commercially exploit the Licensed Technology.

Past Patent Costs means the past patent costs set out in Schedule 2.

Project means the project referred to in BACKGROUND.

Quarter means each period of three calendar months during a Licence Year with the first Quarter commencing on the first day of each Licence Year.

RPI means the Retail Prices Index for all items which is published in the United Kingdom by the Office for National Statistics, or any replacement of it.

Royalty Rate means the royalty rate or rates set out in Schedule 2.

Royalty Report means the report to be prepared by the Licensee under clause 11.2.

Signing Fee means the signing fee set out in Schedule 2.

Step-Down Royalty Rate means the royalty rate or rates set out in Schedule 2.

Territory means the territory or territories set out in Schedule 2, excluding any territory or territories removed through the operation of clause 6.3.

University means the Chancellor, Masters and Scholars of the University of Oxford whose administrative offices are at the University Offices, Wellington Square, Oxford OXl 2JD.

Valid Claim means a granted or currently pending claim included in the Applications that has not expired nor been held permanently revoked, unpatentable, invalid or unenforceable by a court or tribunal of competent jurisdiction in a final and non-appealable judgment; nor been rendered unenforceable through disclaimer or otherwise abandoned.

Schedule 2

Applications:	OUI project 13709: Influenza A haemagglutinin antigen Group 1 (Hl) - site of limited variability International Patent Application No. PCT/GB2017 /052510, which was filed on 25th August 2017 entitled “lmmunogenic composition”
Additional Applications:	OUI Project 16867: Influenza A haemagglutinin antigen Group 2 (H3) - site of limited variability QUI Project 16870: Influenza Group B haemagglutinin antigen - site of limited variability QUI Project 16872: VLP delivery system for influenza vaccine
PCT National Phase filing deadline:	25th February 2019
Inventor:	Craig Thompson and Sunetra Gupta
Territory (clause 3.1):	Worldwide
Field (clause 3.1):	All fields
Documents (clause 3.2):	The Applications.
Past Patent Costs (clause 6.1):	£11,323.00
Signing Fee (clause 9.1): Royalty	$0
Rate (clause 9.2):	6%
Step-Down Royalty Rate (clause 9.3):	50% of Royalty Rate

Minimum Sum (clause 9.4

Licence Year	(Annual) Minimum Sum
Years 1- 3	[***]
Year 4 - Year pre-Phase Ill	[***]
Year of Phase Ill - Year of Launch	[***]
Years Post Launch - Year Step down Royalty applies	[***]
Once Step-Down Royalty applies	[***]

Fee Income Royalty Rate (clause 9.5): 25%

Milestone and Milestone Fee (clause 9.6):

Milestone	Milestone Fee
Initiation of first Phase I study	[***]
Init iation of fi rst Phase II study	[***]
Initiation of Phase Ill/pivotal registration studies	[***]
First submission of application for Regulatory Approval (BLA/NDA)	[***]
Marketing authorisation in USA	[***]
Marketing authorisation in any EU country	[***]
Marketing authorisation in Japan	[***]
First M arket ing authorisation in any ROW country	[***]
First commercial sale in US	[***]
First commercial sale in any EU country	[***]
First commerc ial sale in Japan	[***]
First commercial sale in any ROW country	[***]
First year that Annual sales equal or exceed $500,000,000	[***]
First year that Annual sales equal or exceed $1,000,000,000	[***]

RPI on date of this agreement (clause 9.8): 289.2

Licensee's Contact and Address (clause 14.6):

Contact	Joe Hernandez
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email	hernandez joe@y ahoo.com

Schedule 3

DEVELOPMENT PLAN

Document entitled: “Process Development and CGMP Manufacturing of Recombinant Influenza Conserved Regions for Vaccine Production” from Ology Bioservices dated 22nd May 2019.

PROCESS DEVELOPMENT AND CGMP MANUFACTURING OF RECOMBINANT INFLUENZA CONSERVED REGIONS FOR VACCINE PRODUCTION

***REVISION 02;* MAY 22, 2019**

Prepared for and Accepted by:
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Signature **Date**

Printed Name **Title**

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Timothy Cooke 22 May 2019
Signature **Date**

Proposed Period of Performance: July 2019 – July 2021
Contract Type: Firm Fixed Price
Proposal Validity Period: 60 Days

This proposal, furnished in response to a request from Blue Water Vaccines, Inc., may contain trade secrets and/or privileged or confidential commercial or financial information. This information is maintained in confidence in the course of the Offeror's business and is not otherwise publicly available. The Offeror submits this information to Blue Water Vaccines, Inc. in confidence and understands that it is received with that intent.

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EXECUTIVE SUMMARY

Ology Bioservices, Inc. (Ology Bio) welcomes the opportunity to perform Process Development and CGMP Manufacturing of Recombinant Influenza Conserved Regions for Vaccine Production for Blue Water Vaccines, Inc. (Blue Water). Blue Water is currently developing a novel influenza vaccine based on four conserved regions of the influenza virus. Each of these conserved regions encodes a unique 15-20 amino acid peptide sequence. Blue Water has demonstrated the each of these peptides is highly immunogenic and conserved over many different strains of influenza. These peptides are currently being combined into a single large polypeptide vaccine candidate and expressed in E coli. The present scope of work includes the timely process development and manufacture of the novel influenza vaccine candidate suitable for pre-clinical animal studies and Phase 1 clinical studies. The proposed schedule, assuming a start date of July 8, 2019, and material pricing of the outlined work are provided in Sections 3.0 and 4.0, respectively. The estimated budget for the outlined work is $4,325,012, including raw materials and supplies and an IND-enabling nonclinical study.

1.0 PROJECT OVERVIEW

1.1 Project Scope:

This proposal consists of eight Tasks required to manufacture and release a CGMP lot of Drug Substance (DS) and Drug Product (DP) suitable for Clinical Development and conduct preclinical IND-enabling studies and prepare the IND. Specific details of each task are provided in Section 2.0. Ology Bio will work collaboratively with Blue Water and Ology Bio's qualified subcontractors to provide a comprehensive program using experienced scientists. To meet the requirements of this project, we have assembled a highly qualified and experienced team of Subject Matter Experts (SMEs) with domain expertise in all disciplines required to successfully accomplish the scope of work.

Task 1: Technology Transfer and Process Establishment
Task 2: Analytical Assay Development
Task 3: CGMP Master Cell and Working Cell Banking
Task 4: Process Development and Scale-up
Task 5: Engineering Run and Stability Testing
Task 6: CGMP Run and Stability Testing
Task 7: Drug Product Engineering and CGMP Drug Product
Task 8: Regulatory Support for Preclinical IND-Enabling Studies and IND Preparation

1.2 Company Overview:

Ology Bio is a privately held company founded in 1999 as an integrated biopharmaceutical company with a focus on product development and manufacturing. Ology Bio has capabilities in analytical development and validation, process transfer, development and scale-up, formulation optimization, CGMP manufacturing and regulatory services for development of biopharmaceutical products and medical devices through licensure. Ology Bio has several proprietary platform technologies that can be used with all drug types, including but not limited to small molecules, proteins, monoclonal antibodies and vaccines.

Ology Bio has existing capabilities with internal expertise or specialized expertise of our contractors/teaming partners to successfully execute each stage of the development program. The capabilities include established processes and procedures for Program Management, Technology Transfer, Process Development, CGMP Formulation and Fill, Quality Control (QC), Quality Systems (QS), and Regulatory Chemistry, Manufacturing and Controls (CMC) technical writing support. The ADM Facility provides the following features:

- Accommodation of Single-use Technologies (SUTs) to provide significant advantages in cost, operational flexibility, and reliability
- Process Development Laboratories to accommodate small and pilot-scale development work and engineering runs including capability for BSL-3 agents
- QC in-process testing and release capability

- Agile, flexible manufacturing based on single-use, skid-mounted process equipment in both pilot plant and manufacturing core to facilitate the rapid changeover of process configurations for different platform technologies within production suites
- Four CGMP suites providing concurrent production capacity.

As required to fulfil the scope of a project, Ology Bio will also engage the specialized services of our highly experienced and QA qualified contractors for specific scope in the project (DP formulation and fill, outsourced testing, shipping).

2.0 TECHNICAL APPROACH AND PLAN

Task 1: Technology Transfer and Process Establishment

Table l. Task 1 Technical Assumptions

Technical Assumption(s)
Product-specific information (e.g., Bill of Materials, previous run data, intermediate stability data, any regulatory documentation, test methods) will be transferred within 5 business days of contract signing.
The kick-off meeting will be scheduled within 10 business days of contract signing.
Two Process Establishment runs will be performed at this stage using the established methodology provided by Blue Water.
Blue Water will provide Research Cell Bank vials, reagents and standards and associated Certificates of Analysis, as required, to Ology Bio within 5 days of contract signing

Information Transfer and Gap Assessment:
The Information Transfer stage is critical for the success and timeliness of the project. Ology Bio requests that all pertinent documents from Blue Water will be supplied within 5 days of contract signing to allow enough time for critical review by the Ology Bio team. A kick-off meeting will be scheduled with review of the plans and timelines. After the project gap analysis is complete, a final schedule and Gantt chart will be completed.

Receiving Blue Water Documentation:
To initiate the Technology Transfer, we will conduct a thorough review of all process and analytical documents provided by Blue Water. In collaboration with Blue Water, we will create a Development Plan and governance process to meet the objectives of the project. Blue Water will provide Ology Bio with all applicable standard operating procedures (SOPs), process procedures, process transfer protocols, analytical plans, specifications and other knowledge to transfer analytical methods and the manufacturing process. Technology Transfer will include the following preparation activities:

- Preparation of a Development Plan
- Preparation of documentation
- Equipment Identification
- Flow diagrams as appropriate
- Process step descriptions
- Risk Analysis and Mitigation Strategy

Transfer of Product-Specific Materials from Blue Water and Procurement of Materials and Components:
Blue Water will provide Research Cell Bank (RCB) vials, reagents and standards, and associated Certificates of Analysis (COAs), as required, to Ology Bio within 5 days of contract signing in order to stay within the aggressive timeline for this program.

A full list of raw materials will be developed and sent to Blue Water for approval. All consumables, expendables and raw materials will be purchased using QA-approved vendors, properly inventoried and stored in the proper conditions. We may elect to purchase pre-prepared media and certain buffers from agreed-upon suppliers to avoid any variability in these critical reagents in the process. We will identify and qualify suppliers of production materials and any required excipients. The nature of this project will require that additional materials identified in the Process Development Task to be communicated to Blue Water at a later date.

Development Plan and Reports:
Weekly or biweekly presentations will be provided to Blue Water that summariz.es the performance of the process per plan. At the end of Task 1, a draft Development Plan will be written and reviewed/approved by both Ology Bio and Blue Water. The Development Reports will be written after execution of Establishment Runs to contain details on each unit operation; trending of the data compared with any available historical data (i.e., provided in Blue Water documents); analytical testing results; process deviations and impact assessment; our proposed process changes, including assessment of impact and justifications for changes; and updated risk and gap assessment.

Process Establishment:
Ology Bio will perform two Process Establishment Runs to demonstrate the process for the Blue Water influenza vaccine candidate at laboratory scale (1 L shake flask) and prepare a process transfer final report for approval by Blue Water. Ology Bio will use the existing RCBs from Blue Water to perform these runs. Ology Bio proposes to remove the His-tag from the existing vaccine candidate in Task 4. Upstream and Downstream Process Flow Diagrams for the production of the Blue Water influenza vaccine candidate are shown in **Figure 1** and **Figure 2**.

Figure 1. Upstream Fermentation Process

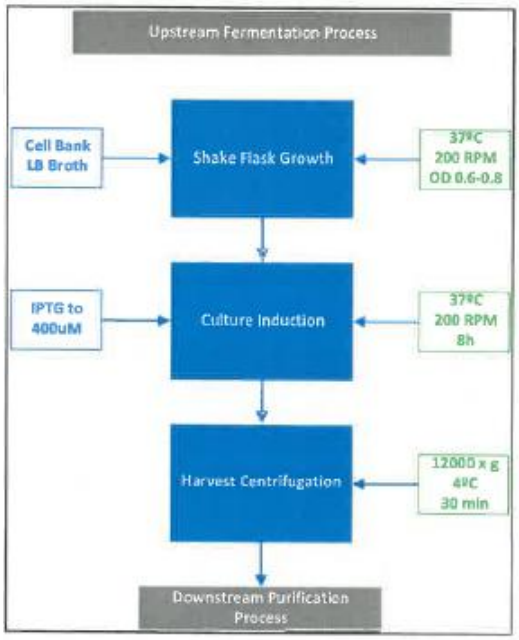
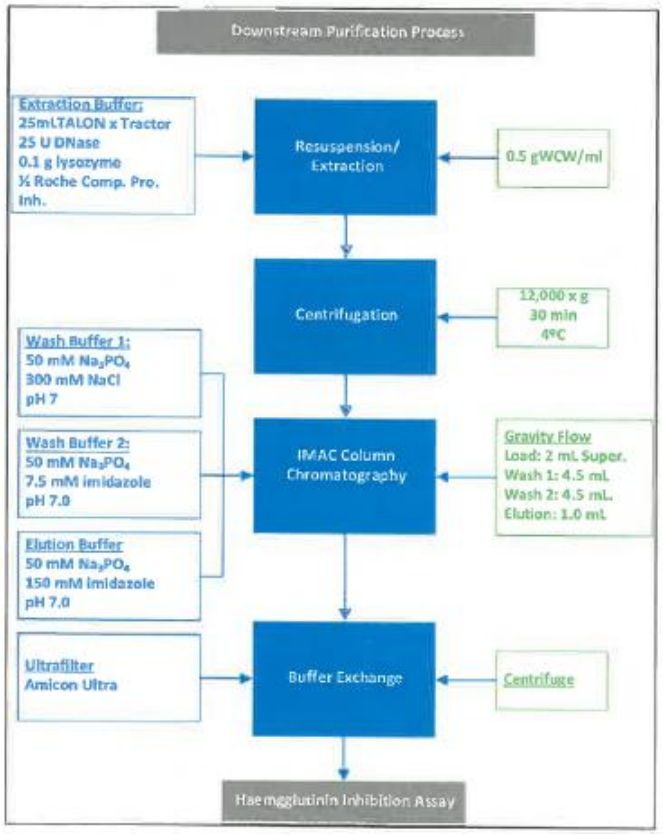


Figure 2. Downstream Process Flow Diagram



Limited testing will be performed on these Establishment runs. These will include SDS PAGE, protein concentration and HPLC analysis for purity. We will also present a preliminary Bill of Materials (BOM) at the end of this task.

A list of deliverables for Task 1 is shown in **Table 2**.

Table 2. Task 1 Deliverables

Task	Deliverable
Task 1: Technology Transfer and Process Establishment	Final Schedule Agreement with Blue Water and Ology Bio at completion of this stage
	Project Management Plan including Project Charter
	Meeting agenda and minutes
	Process development plan
	Process establishment plan and report
	Preliminary Bill of Materials

Task 2: Analytical Assay Development

Table 3. Task 2 Technical Assumptions

Technical Assumption(s)
Blue Water will provide analytical Reference Standard, product-specific reagents (antibodies) and initial samples of DS and DP for use in method transfer and validation
All required analytical methods are summarized in **Table 4**
Assay qualification will be phase appropriate
Forced degradation studies will not be required on DS

A complete list of analytical assays will be provided by Blue Water or agreed upon with Ology Bio. Specifications for each of the assays will also be provided by Blue Water or agreed upon with Ology Bio. We propose to perform Technology Transfer feasibility assessments on the QC assays outlined in **Table 4** for in process (IP) testing and DS testing. Stability and DP testing are described in Tasks 6 and 7, respectively. Following the Technology Transfer feasibility assessment, QC scientists will revise method SOPs (as required) and verify methods for testing. Upon completion of the verification studies, a comprehensive report, reviewed and approved by QA, will be provided documenting the results of the verification, the suitability of the intended method, a description of test samples, a description of experiments and a summary of data for each parameter tested, as well as relevant raw data obtained from these studies. These assays will also be qualified as suitable for CGMP release and use in Phase 1 clinical trials. Testing will not be outsourced without the prior written consent of Blue Water.

Table 4. In-Process and Drug Substance Release Testing

Assay	Method	Location	Specification	Process Step
Physiochemical Properties				
Appearance	Visual Observation	Ology Bio	Clear, colorless liquid; no particles	DS
pH	USP<791>	Ology Bio	TBD	IP, DS
Conductivity	TBD	Ology Bio	TBD	IP
Viability	Cell count	Ology Bio	TBD	IP
Safety				
Endotoxin	USP<85>	Ology Bio	< 10 EU/dose; dose = 100 µg	IP, DS
Cytolytic Activity	Hemolytic Assay	Blue Water	TBD	DS
Bioburden	Membrane Filtration	Ology Bio	< 10 CFU/mL	IP, DS
General Safety	21 CFR 610.11	Ology Bio	Pass	DS
Content				
Protein Concentration	BCA	Ology Bio	Report	IP, DS
Identity				
Presence of Blue Water Vaccine Candidate[1]	Western	Ology Bio	Identity Confirmed	IP, DS

Assay	Method	Location	Specification	Process Step
Purity				
Purity	SDS-PAGE	Ology Bio	TBD	IP, DS
Host Cell DNA	*E. coli* qPCR assay	Ology Bio	TBD	DS
Host Cell Protein	Kit	Ology Bio	TBD	DS
Potency				
In vitro immunopotency	ELISA	Blue Water	TBD	DS

1 Assay will be Tech Transferred to Ology Bio

A list of deliverables for Task 2 is shown in **Table 5.**

Table 5. Task 2 Deliverables

Task	Deliverable
Task 2: Analytical Assay Development	Analytical assay Qualification Plan for each analytical method
	QA-reviewed and approved Qualification Report for each analytical method
	In-process and release assay specifications

Task 3: CGMP Master and Working Cell Banking

Table 6. Task 3 Technical Assumptions

Technical Assumption(s)
A minimum of 300 CGMP MCB vials will be prepared in support of this project
A minimum of 300 CGMP WCB vials will be prepared in support of this project
RCB required for MCB production will be generated at Ology Bio in Task 4

In compliance with CGMP Regulations, Ology Bio will produce a minimum of 300 vials of a Master Cell Bank (MCB) per QA-approved batch production records using the RCBs generated by Ology Bio as part of Task 4. The new Blue Horizon vaccine candidate will not contain a His-tag. These RCBs will be utilized for the production of the CGMP MCBs. The new MCB will undergo characterization and release testing based on an analytical control strategy outlined in **Table 7**. Ology Bio proposes to generate CGMP Working Cell Banks (WCBs) from the MCBs and characterize them.

Table 7. Cell Bank Release Assays

Cell Bank Release Assay
Strain ID/Purity-Differential Media
Product ID-Dot or Western or SDS-PAGE
Viability
Growth Stability
Plasmid Sequencing
Plasmid Size
Genetic Stability-Copy Number
Genetic Stability-Plasmid Restriction Analysis
Plasmid Retention/Antibiotic Resistance
Bacteriophage

An annual stability program will also be initiated and will be continued for up to three years for both MCB and WCB. For budgeting purposes, testing will only be conducted for 12 months, but cells will remain on stability for future testing. The stability testing is provided in **Table 8**.

Table 8. Cell Bank Stability Assays

Cell Bank Stability Assays
Growth Stability
Viability
Genetic Stability-Plasmid Restriction Analysis
Plasmid Retention/Antibiotic Resistance

Table 9. Task 3 Deliverables

Task	Deliverable
Task 3: CGMP Master and Working Cell Banking	Summary Report on cell banking and release for both MCB and WCB including COAs and copies of Master Batch Records
	Cell bank stability plan for MCB and WCB for review and approval by Blue Water
	A minimum of 300 CGMP MCB vials
	A minimum of 300 CGMP WCB vials

Task 4: Process Scale-up and Optimization

Table 10. Task 4 Technical Assumptions

Technical Assumption(s)
The Process Development Plan outlining the experimental plan will be approved by Blue Water
Successful Process Establishment Runs were completed in Task 1
Process Development will include development of a non-His-tagged influenza vaccine candidate
Process Development will include generation of new RCBs
Five process development runs at the 3 L scale will be performed
Two scale-up runs at the 120 L scale will be performed

Based on the results observed from the Process Establishment runs, we will redesign the expression system to remove the His-tag from the coding region of the vaccine candidate. The new plasmid will be evaluated using two different E coli expression systems: one based on IPTG induction, the other based on phosphate depletion (PhoA). The expression system that yields the highest soluble titer will be selected for further development. We will initially generate RCBs. We will identify three individual colonies, and each of the colonies will be analyzed for protein production at the 1-3 mL scale. Two colonies will be scaled up and used to generate SO vials of RCB. These RCBs will then be utilized for production of the CGMP MCBs and WCBs as described in Task 3. Each RCB will be characterized as per **Table 11**.

Table 11. RCB Release Assays

Release Assays
Viability
Growth Stability
Plasmid Size
Genetic Stability-Plasmid Restriction Analysis

These RCBs will be used for the initial process development studies. The process development will focus on both the upstream and downstream processing of the vaccine candidate. Small-scale upstream production runs (1 L scale) will be used to generate materials for the downstream processing. Ology Bio proposes to use their rapid chromatography screening protocols to identify and optimize the chromatographic procedures required for the purification of the Blue Water vaccine candidate. Ology Bio proposes to scale-up the manufacturing process to the 120 L scale to generate the required 1-2 grams required for this project. This will include five 3 L production runs to identify the optimum upstream parameters for maximum production of the vaccine candidate.

In parallel, the downstream processing will be optimized as described above and then scaled to the 3 L scale. Ology Bio then proposes to perform two scale-up runs at the 120 L scale using the 150 L stainless steel fermenter, the proposed manufacturing production scale. These runs will be analyzed using the in-process and release tests as described in Task 2. Success criteria for these runs will be agreed upon by Blue Water and Ology Bio prior to initiation of these runs. The sampling plan for these runs will also be agreed upon prior to initiation of the runs. Draft batch records and a final sampling plan will be prepared for use in the Engineering runs (Task 5).

Equipment required to support all the required tasks for the program are in-place and have been previously qualified at the ADM Facility, as listed in **Table 12**. Should additional equipment be required, qualification will be performed per standard operating procedures prior to CGMP manufacturing.

Table 12. Equipment list for DS Manufacturing at the ADM Facility

Item	ADM Equipment Identification
Analytical scale	Fisher XS2002S
Autoclave	Fedegari Autoclave Model NA2420AW
Centrifuge	Sorvall LYNX 6000
Freezer	Revco High Performance -20° C Freezer
Mixing Vessels	GE XDM-Quad Mixing Systems (50-500 L)
Depth Filtration Systems	Millipore POD, 3M and Sartorius Holders available
Chromatography System	GE Akta Ready
TFF System	Sartorius Sartoflow Alpha Plus and Flex Act
Fermentor	Eppendorf BioFlo Pro 120 L and 60 L
Incubator Shaker	Eppendorf I42R
Mini Fermentor System	Eppendorf
Microscope	Fisher LMI-6001B
Pump(s)	W/M Peristaltic Pump, 520SN/R2; W/M Peristaltic Pump,520 Um AN/R2; W/M Peristaltic Pump, 323S/RL2
Refrigerator	REL4504A Revco High Performance Refrigerator
Scale	ABSCO SIWSDCS-1-35H-E7
Waterbath(s)	Fisher Scientific Model 265/2866
Vapor phase liquid nitrogen freezer	Forma 7402 CryoPlus
Stir plate	Corning PC-240
pH meter	Orion Versa Star Meter, pH/Conductivity
Balance	ABSCO SIWSDCS-1-35H-E7
Conductivity meter	Orion Versa Star Meter, pH/Conductivity
Class B Laminar Flow	NuAire BSC NU-430-600
Pipette Aid	Numerous
Micropipettor (200µL)	Numerous
Micropipettor (1000µL)	Numerous
Freezer ≤ -70° C	Thermo UFX600
Autoclave for decontamination	Fedegari NA2421AW
Multipette	Numerous
Balance	ABSCO SIWSDCS-1-35H-E7

Deliverables for this task are provided in **Table 13**.

Table 13. Task 4 Deliverables

Task	Deliverable
Task 4: Process Development and Scale-up	Process Development Report for Blue Water review and approval
	Material from the Process Development Runs
	Process scale-up final report for review and approval by Blue Water
	Materials from the Scale-up runs

Task	Deliverable
	Process parameters for the Engineering run
	Technology Transfer Protocol
	Draft batch records and sampling plan for use in the Engineering run
	Confirmation Run report and materials

Task 5: Engineering Run and Stability Testing

Table 14. Task 5 Technical Assumptions

Technical Assumption(s)
Ology Bio proposes to perform one Engineering run at the 120 L scale
In-process and release testing will be performed as described in Task 3
Materials will be placed on 12-month stability
DS Reference Standard materials will be generated (1,000 vials)

We will perform one Engineering run at full scale of 120 L. The in-process and release testing plan for this run will be agreed upon by Blue Water and Ology Bio. The Engineering run will be executed at the 120 L production scale by manufacturing staff in the CGMP manufacturing core at the Facility. The Engineering run will be performed using draft Master Batch Records and QA-released raw materials and components. The batch records will be redlined during the Engineering run, and any changes will be incorporated into the Master Batch Records prior to approval for CGMP manufacturing. The in-process and release assays are described in Task 3, **Table 4**.

The material generated from this lot will be indicative of the COMP-manufactured material. The materials from this lot will be made available to Blue Water for additional studies. In addition, materials from this lot will be used to generate Reference Standard materials. ACOA and Material Safety Data Sheet (MSDS) will be prepared at this stage. A completed BOM will be submitted as part of this Stage. The non-CGMP OS material will be placed on stability studies.

Stability Testing:
Stability testing of non-CGMP Engineering DS will be conducted in accordance with current U.S. FDA Code ofFederal Regulations (CFR) and International Conference on Harmonization (ICH) guidelines, including:

- 21 CFR Parts 210 and 211 (CGMPs)
- 21 CFR Part 312 (IND Application)
- ICH Q1 A(R2) Guideline: “Stability Testing ofNew Drug Substances and Products,” February 2003
- ICH QlC Guideline: “Stability Testing of New Dosage Forms,” November 1996
- ICH QSC Guideline: “Stability Testing of Biotechnological/Biological Products,” November 1995

The stability evaluation will support the following:

- Use of the investigational product throughout nonclinical studies and clinical trials
- Mitigation of shipping and storage temperature excursion impact on the investigational product
- Stability of the product during handling (clinical sites, emergency-use scenarios)
- Selection of lot release and stability-indicating analytical test methods
- Expiration or retest dates for OS
- Product conformity to stability specifications throughout the clinical trial

The proposed stability study for non-CGMP (as well as CGMP) OS lots is provided in **Table 15**. Stability testing will be conducted per approved protocols and reported annually.

Table 15. Drug Substance Stability

Test	Location	Acceptance Criteria	0m	1m	3m	6m	9m	12m
pH	Ology Bio	TBD	x	x	x	x	x	x
BCA	Ology Bio	TBD	x	x	x	x	x	x
SDS-PAGE/Western blot/ densitometry to monitor protein degradation	Ology Bio	TBD	x	x	x	x	x	x
Sterility	Ology Bio	No fungal or bacterial growth observed	x					x

Reference Standard:
Providing high-quality, documented and qualified Reference Standards is critical to every batch released, and characterization can be an arduous process. In accordance with our QS, Reference Standards are produced and qualified prior to use in lot release, characterization or stability testing. The objective of this program is to provide complete documentation of the establishment and trending of product Reference Standards. Another goal of the program is to assess the suitability and availability of Reference Standards and critical reagents to meet ICH and FDA guidelines appropriate for the product lifecycle stage for which the materials will be used. This program results in complete documentation of these Reference Standards by providing:

- Manufacture according to approved batch record or protocol
- Qualification according to approved qualification protocol
- Lot release testing according to approved technical specification
- Generation of a COA detailing the lot release testing results
- Controlled storage conditions and inventory
- Stability testing
- Continual data trending and evaluation of suitability in new/revised analytical methods and/or with changes to manufacturing process operations

For the Blue Water program, interim DS Reference Standards will be established in accordance with an approved protocol from the DS Engineering lot(s). To reiterate the approach to DS Reference Standard, a minimum of 1,000 vials of Engineering DS will be aliquoted and qualified as the DS Reference Standard. The filled Engineering DP generated in Task 7will be labelled and qualified as the DP Reference Standard. AQA-reviewed and approved Qualification Report will be provided that documents suitability of the DS and DP Reference Standards in the intended methods. These interim DS and DP Reference Standards are to be used for Phase 1/2 product lot release and stability testing.

A list of deliverables for Task 5 is shown in **Table 16**.

Table 16. Task 5 Deliverables

Task	Deliverable
Task 5: Engineering Run and Stability Testing	DS Engineering Report
	DS Engineering Stability Protocol/Report
	Finalized BOM
	Finalized CGMP batch record templates
	Finalized CGMP DS Specifications
	Engineering non-CGMP DS COA and MSDS
	Updated Tech Transfer Protocol (if needed)
	Engineering non-CGMP DS Product

Task 6: CGMP Run and Stability Testing

Table 17. Task 6 Technical Assumptions

Technical Assumption(s)
Ology Bio CGMP WCB produced will be used
Ology Bio will perform one CGMP DS lot at the 120 L scale

Table 17. Task 6 Technical Assumptions

Blue Water and Ology Bio will agree on the analytical and IP testing plan for the routine production of the Blue Water vaccine candidate, which we will implement. Following completion of the scalability studies, a Technology Transfer Protocol will be generated. This report will describe the process development and define the critical process parameters and established ranges. The report will summarize lot testing and establish a sampling and testing plan to be used during COMP manufacturing. A BOM listing all required raw materials and components will be included. From this BOM, specifications will be created for each material, as well as for IP intermediates where required. Batch records will be finalized and approved by QA for use in the CGMP manufacturing campaign. Any changes identified during the execution of the DP Engineering run (Task 7) will be incorporated into the final CGMP batch records prior to execution.

We will perform one COMP manufacturing campaign in accordance with:

- 21 CFR Parts 210 and 211 (CGMP)
- 21 CFR Part 312 (IND Application)
- 21 CFR Parts 600 and 610 (Biological Products)
- 21 CFR Part 11 (Electronic Records and Signatures)

To lead to a successful campaign, we will use manufacturing readiness reviews to ensure that all activities are completed prior to the start of manufacturing. We perform Area Clearance and Product Changeover according to internal SOP-09-00054. Trained Operations personnel will clear manufacturing areas after manufacturing campaigns following work instruction WI-09-00004. Areas are cleaned according to SOP-09-00006, including chlorine dioxide decontamination when appropriate. Activities are documented on forms and manufacturing areas are released for use after QA review of these activities.

Our QA takes responsibility for assuring the quality and integrity of products and all data generated in compliance with the FDA GLPs and CGMPs. QA provides review of manufacturing and testing operations as well as approval of specifications, Master Batch Records, procedures, contract manufacturers, system and equipment changes, and intermediate and final product release. Deviations and investigations are integrated in a corrective action system. QA review and approval activities will be carried out in support of CGMP production campaigns on all the following activities:

- **Documentation:**
  - Raw Material Specifications
  - Manufacturing Master and Executed Batch Records
  - Equipment Operation and Maintenance SOPs
  - Analytical Method SOPs
  - Cleaning and Disinfection SOPs
  - Harvest and Final Product Specification

- **Manufacturing Cleanroom Preparation:**
  - Cleaning of Laboratory during Manufacturing
  - Area Clearance and Product Changeover
  - QA Audits
  - Cleaning Validation Risk Assessment/Protocol, if applicable

- **Reference Standard:**
  - Certification of Reference Standard

- **Raw Materials:**
  - Vendor Qualification
  - Ordering of Raw Materials and Supplies
  - Sampling of Raw Materials
  - QC Testing of Raw Materials and Data Review
  - QA Audit of Testing Data and Raw Material COAs
  - QA Release of Raw Materials and Inventory Tracking
- **CGMP Manufacturing:**
  - Manufacturing of DS
- **Product Testing:**
  - QC Review of Testing Data
  - QA Review of Testing Data and Preparation of COAs
  - QA Release of DS Lot(s)
- **Packaging and Shipping:**
  - Packaging and Shipping of DS
- Project Audit and Final Report

Documentation:
We have a validated electronic Quality Management System, MasterControl, to automate and integrate processes for meeting quality standards and complying with regulatory requirements. Master Control manages documents, training and risk; processes and audits; and facility and equipment calibration and maintenance program. Documentation in MasterControl includes, but is not limited to, raw material specifications, product specifications, MPR, equipment operation SOPs, and analytical method SOPs and protocols.

CGMP manufacturing will be performed in compliance with CGMP regulations, including approved Master Batch Records, CGMP cell banks, active environmental monitoring and QA release of all raw materials and consumables. Raw materials will be purchased using QA-approved material specifications from QA-approved suppliers in accordance with our Supplier Selection, Assessment and Approval procedures (SOP-20-00018). CGMP runs will be performed in the manufacturing core using the same equipment, facilities and personnel as utilized for the Engineering Run.

Production:
Trained manufacturing personnel will execute one CGMP production lot in accordance with QA-approved production records and SOPs. The CGMP runs will be performed in the manufacturing core using the same equipment, facilities and personnel as utilized for the Engineering run. The manufacturing core features ISO 8 in-operation (Grade C) processing rooms for all closed system operations. All open manipulations will occur within the ISO 5 area (Grade A BSC) located within an ISO 7 in-operation (Grade B) suite adjacent to the main processing room. Samples will be taken throughout the manufacturing process according to the batch record and product specifications. The process will be executed aseptically from start to finish, as demonstrated in the process simulation as part of Task 7. Bulk DS will be stored at ≤ -70°C fill/finish at Ology Bio.

The CGMP material will be tested according to the OS specifications and tests previously defined. QC conducts in-process and lot release testing per SOPs and sampling plans. QA will provide the final review of batch records, environmental monitoring and analytical results. QA will also provide release of CGMP OS via a COA, ensuring that the DS product lot meets all technical specifications and is acceptable for use in GLP, nonclinical studies and Phase l clinical studies.

Ology Bio will perform limited stability testing as outlined in Task 5 and will provide samples as defined. A list of deliverables for Task 6 is shown in **Table 18**.

Table 18. Task 6 Deliverables

Task	Deliverable
Task 6: CGMP Run and Stability Testing	QA-Approved Batch Production Records
	QA-Approved COA(s) (per lot)
	Stability testing samples, data and reports
	Campaign summary report
	DS materials for DP formulation

Task 7: Drug Product Engineering and CGMP Drug Product

Table 19. Task 7 Technical Assumptions

Technical Assumption(s)
Maximum DP lot size is 2,000 single-dose vials per lot
Intended DP storage temperature is < -20°C
DP will include an adjuvant provided by Blue Water with the final formulation
DP process qualification runs will be required

After completing the DS Engineering run, we will execute an Engineering run of the DP filling process using the final container and closure method agreed upon with Blue Water (anticipated to be a 2 mL vial). The final formulation will include an adjuvant provided by Blue Water. DP vials will be tested according to developed release criteria (**Table 20**) and placed on limited stability studies (**Table 21**).

Table 20. Drug Product Release Assay

Assay	Method	Location	Specification
Physiochemical Properties			
Appearance	Visual Observation	Ology Bio	Clear, colorless liquid; no particles
pH	USP<791>	Ology Bio	7.4 ±0.3
Osmolality	USP<785>	Ology Bio	250 – 350 mOsmol/kg
Safety			
Endotoxin	USP<85>	Ology Bio	< 10 EU/dose; dose = 100 µg
Sterility	21CFT610.2	Ology Bio	No growth ≥14 days
Bioburden	Membrane Filtration	Ology Bio	< 10 CFU/mL
General Safety	21CFR610.11	Ology Bio	Pass
Content			
Protein Concentration	BCA	Ology Bio	Report
Identity			
Presence pf Blue Water Vaccine Candidate	Western	Ology Bio	Identity Confirmed
Purity			
Purity	SDS-PAGE	Ology Bio	>95% monomer
Potency			
In vitro immunopotency	ELISA	Blue Water	TBD

Table 21. Drug Product Stability

Test	Location	Acceptance Criteria	0d	1m	3m	6m	9m	12m	18m	24m
Visual Inspection	Ology Bio	No alum – no particles observed	x	x	x	x	x	x	x	x
Visual Inspection	Ology Bio	With alum – white substance with no colored particles	x	x	x	x	x	x	x	x
pH	Ology Bio	6.5 – 7.5	x	x	x	x	x	x	x	x

Test	Location	Acceptance Criteria	0d	1m	3m	6m	9m	12m	18m	24m
BCA	Ology Bio	TBD	x	x	x	x	x	x	x	x
In vitro immunopotenc	Blue Water	TBD	x	x	x	x	x	x	x	x
SDS/PAGE/Western blot/densitometry to monitor protein degradation	Ology Bio	TBD	x	x	x	x	x	x	x	x
Sterility	Ology Bio	No fungal or bacterial growth observed	x					x		x

In accordance with FDA Guidance for Industry, "Sterile Drug Products Produced by Aseptic Processing - Current Good Manufacturing Practice," Sept 2004, aseptic formulation and fill validation (media fill validation) will be conducted using a maximum of2,000 vials per lot in a mutually approved container/closure system (vial, stopper, seal). Three consecutive successful media fill Validation Runs will be performed using TBS to simulate the formulated DP according to an approved media fill validation batch record. In addition, appropriate interventions (extended processing times, simulation of spillage and clean-up of spillage, changing out of the fill needle) will be incorporated into the validation activities.

Phase 1 DP formulation and liquid product fill operations will be conducted at Ology Bio. Using QA-approved production documentation, the DS lot will be formulated to achieve the final concentration of the to-be determined titer in the selected final formulation (determined by Blue Water). Formulated product will be filled into the mutually approved container/closures within an aseptic area. A maximum of 2,000 vials per DP lot will be targeted for filling. QC will conduct lot release testing as summarized in **Table 20** per batch records and sampling plans. QA will provide the final review and release, ensuring that the DP lots meet all technical specifications and are acceptable for use in GLP nonclinical studies and clinical studies. Stability testing of CGMP DP lots is described in **Table 21**.

A list of deliverables for Task 7 is shown in **Table 22**.

Table 22. Task 7 Deliverables

Task	Deliverable
Task 7: DP Engineering and CGMP DP	DP Development Plan
	DP Development Report
	Non-CGMP Engineering Run DP vials suitable for use in preclinical studies
	DP Engineering Summary Report consisting of release testing results
	Media Fill Qualification Report
	Up to 2,000 vials of CGMP DP
	COAs for released CGMP DP
	QA-approved batch production records (per lot)
	QA-approved Campaign Summary Report
	Stability study protocol
	Stability study report

Task 8: Regulatory Support for Preclinical IND-Enabling Studies and IND Preparation

Table 23. Task 8 Technical Assumptions

Technical Assumption(s)
CGMP lot will be used for the toxicity study
Ology Bio assumes that clinical SMEs will be provided by the Sponsor to support protocol development and review
Electronic Publishing costs are not included in this proposal

Subtask 8.1: Pre-Clinical Tox Study

Ology Bio will support Blue Water in the development of a nonclinical safety plan to support IND filing. Based on Ology Bio Regulatory experience, CBER/FDA expects high-quality of material for the IND-enabling toxicity studies that is either CGMP material or comparable to CGMP material. To reduce risk, the schedule linked this study to the CGMP lot. Blue Water can consider risks as it reviews the nonclinical safety plan.

Ology Bio's Nonclinical SME will work with the subcontractor, IITRI to develop a protocol for an IND-enabling study based on feedback received from the FDA during the Pre-IND meeting (Subtask 8.2). Ology Bio will oversee the performance and of a GLP-Compliant Repeat Dose Toxicity Study of the Influenza Vaccine Candidate in Rabbits. The objective of the study will be to determine the immunogenicity, target organ toxicity, and reversibility of the influenza vaccine in rabbits following a repeat dosing regimen to support a Phase 1 clinical study.

Subtask 8.2: Pre-IND Meeting Support

Ology Bio will support a Type B Pre-IND Meeting to ensure successful entry into first-in-man studies. Effective communication with the FDA during the pre-IND stage of product development fosters a strong working relationship and is important for clearance of the IND. Ology Bio Regulatory Affairs (RA) team will respond to information requests received prior to the meeting, support meeting participation and prepare meeting minutes. Our RA team will be engaged in practice sessions to develop responses to potential FDA questions and address concerns to avoid delays in product development. Our RA team tracks risks associated with entry into clinical development and ensures that the meeting reduces risk by proper preparation.

The Pre-IND meeting will include briefing materials describing the Phase 1 Protocol Synopsis; nonclinical toxicity· plan; CMC technical information including cell banking and detailed manufacturing process descriptions; release; and stability information. Specific questions will focus on acceptability of the information to be provided in the IND.

Subtask 8.3: Regulatory Technical Writing

To support Blue Water in developing their IND application, our RA experts will prepare CMC sections for Blue Water's vaccine. Ology Bio will provide Tier I, Tier 2 and Tier 3 regulatory support, which includes technical review of strategic documents (i.e., specifications, change controls, protocols, risk assessments and technical reports) and CMC technical writing. Ology Bio will author the DS CMC information (Quality Modules 3.2.S, 3.2.P and 3.2A) in ICH Common Technical Document (CTD) format, delivered as Microsoft Word documents. CMC technical writing will be limited to manufacturing and testing activities managed by Ology Bio, and placeholders will be included for Blue Water-managed activities. In addition, Ology Bio will support development of Modules 4 and 5 with deliverables provided in Word. Electronic Publishing costs are not included in this proposal.

The Ology Bio RA team is responsible for managing, writing, completing or editing all technical writing assignments; obtaining drop-in documents from the SMEs; assembling all documents and forms into a submission package; and uploading the submission for review and approval. Our RA team works with SMEs as needed to complete editing and addressing reviewers' comments. RA is responsible for working with QA staff to ensure that all information/data has been reviewed for accuracy prior to Client review of documents. For this effort, Ology Bio assumes that clinical SMEs will be provided by the Sponsor to support protocol development and review.

Our RA team uses eCTD Word templates that provide authors with the ability to create documents that adhere to a single standard for consistency to the FDA and to our clients. Scientifically sound and accurate CMC writing to support CTD Module 3 development is critical to the success of the CMC communications with Regulatory authorities. Cost and regulatory operations support for electronic publishing and filing of the IND is not included.

Table 24. Task 8 Deliverables

Task	Deliverables
Task 8: Regulatory Support for Preclinical IND-Enabling Studies and IND Preparation	Preclinical study plan development (PK and toxicity studies)
	Preclinical Protocol Drafts
	Module 3 for CGMP DS and DP
	IND support documentation (MS Word Deliverables)
	Clinical trial documentation to support Phase 1 clinical study (Investigator Brochure and Phase 1 Protocol)

3.0 SCHEDULE AND WORK BREAKDOWN STRUCTURE

The project schedule is presented in **Table 25**. The proposed start date for this project is July 8, 2019; this start date is subject to change based on the date this proposal is accepted and signed and availability of the facility.

Table 25. Project Schedule

Task	Description	Start	End
1	Technology Transfer and Process Establishment	Jul. 8, 2019	Oct. 3, 2019
2	Analytical Assay Development	Jul. 8, 2019	Oct. 24, 2019
3	CGMP Master Cell Banking	Aug. 5, 2019	Nov. 9, 2020
4	Process Development and Scale-up	Sep. 20, 2019	Mar. 5, 2020
5	Engineering Run and Stability Testing	Feb. 21, 2020	Apr. 15, 2021
6	CGMP Run and Stability Testing	Apr 23, 2020	May 27, 2021
7	DP Engineering and CGMP DP	Feb. 28, 2020	Jul. 5, 2021
8	Regulatory Support for Preclinical IND-Enabling Studies and IND Preparation	Apr. 2, 2020	Mar. 3, 2021

4.0 PROJECT BUDGET

Task	Description	Task Price[1]	Pass-Through Costs[2]	Total with Estimated Pass Through
1	Technology Transfer and Process Establishment	$169,702	$7,389	$177,091
2	Analytical Assay Development	$177,900	$30,507	$208,407
3	CGMP Master Cell Banking	$343,909	$17,250	$361,159
4	Process Development and Scale-up	$284,820	$474,407	$759,228
5	Engineering Run and Stability Testing	$294,667	$186,674	$481,341
6	CGMP Run and Stability Testing	$375,023	$283,791	$658,815
7	DP Engineering and CGMP DP	$519,306	$91,181	$610,487
8.1	Pre-Clinical Tox Study and Protocols	$163,911	$325,000[3]	$488,911
8.2	Pre-IND Meeting Support	$253,155	$0	$253,155
8.3	Regulatory Technical Writing	$326,420	$0	$326,420
TOTAL		**$2,908,813**	**$1,416,199**	**$4,325,012**

1 Task prices are based on estimated time.
2 Material costs are estimated for budgeting purposes and include a 15% material handling fee.
3 GLP compliant IND-enabling tox study performed by Ology Bio subcontractor

APPENDIX A- GENERAL ASSUMPTIONS

The schedules, estimates and costs contained within this proposal are based on the Listing of Technical Assumptions and the following General Assumptions. If any of these assumptions are incorrect, Ology Bio reserves the right to re-estimate both the schedule and the cost for this proposal.

1 Ology Bio technological proposal is a suggested pathway based on the information provided. Additional and/or replacement of the techniques as result of new and/or more (or less) detailed information from Blue Water may affect the content and pricing of this proposal.
2. Blue Water will make available the appropriate SMEs and stakeholders as needed.
3. Blue Water will provide sufficient materials required to begin assay development.
4. Ology Bio assumes that active and responsive participation and availability by Blue Water SMEs, stakeholders, etc., will exist throughout the length of this project in support of project scope, schedule, and team.
5. Access to development/practice/test documents will be available at contract start.
6. Full cooperation and conditions obtained from any/all applicable external third parties (manufacturers, service providers, leasers, etc.) required by the scope of this project will be acceptable to Ology Bio. Unfavorable conditions (terms, costs, etc.) will require that alternative solutions be found.
7. Timelines are bound to the specific period outlined in this proposal. As such, the appropriate space and resources will be allocated to this project during that timeframe. In the event of delays resulting in activity or inactivity of Blue Water, additional charges and an extension of the timeline may become necessary.
8. Ology Bio will work in good faith based on agreed upon terms and in cooperation of the needs of Blue Water. All activities associated with this project remains at the discretion of Ology Bio.
9. A mutually agreed-upon Decision Log will be used to make and record non-substantial changes/modifications to the contract without the need for a complete formal amendment. The Decision Log will be referenced as incorporated into the contract.
10. This estimate is valid for 60 days and until this proposal is signed as a contract document and agreed upon by both parties. Ology Bio reserves the right to adjust pricing based on new data, market cost fluctuations, and additional work requested by Blue Water prior to execution of the contract.

APPENDIX B- FACILITIES AND EQUIPMENT

Ology Bio operates a 180,000 ft^2 multi-purpose, multi-product biologics and vaccine facility in Alachua, FL. Ology Bio provides capabilities for analytical testing, scale-up and development, CGMP cell and viral banking and storage, and CGMP manufacturing with the ability to handle pathogens at biosafety levels up to BSL-3. The main functions of the DoD Advanced Development and Manufacturing (ADM) Facility include testing, developing and CGMP manufacturing of biologics including:

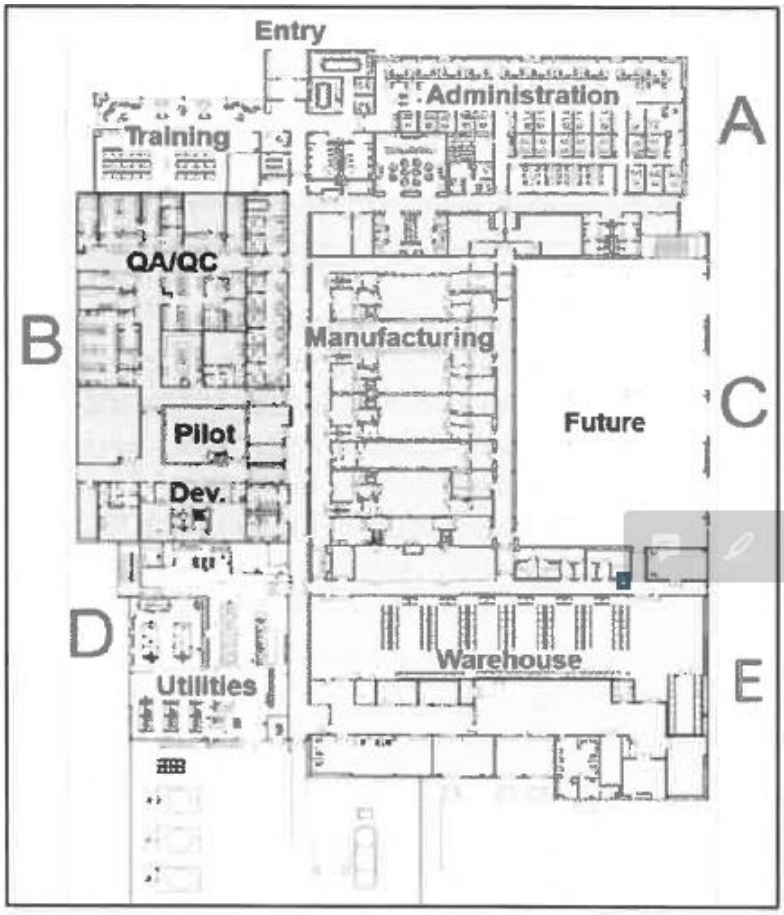
- Vaccine products (bacteria, viruses and virus-like particles)
- Monoclonal antibodies from cell culture
- Recombinant proteins from various expression platforms (*E. coli*, yeast, insect, and mammalian cells)
- Master and Working Cell and Viral Banks
- Concurrent manufacturing of multiple CGMP bulk biologics via four independent production rooms

The ADM Facility provides the following features:

- Accommodation of SUTs to provide significant advantages in cost, operational flexibility, and reliability
- Availability of traditional stainless-steel equipment capable of clean in place and sterilize in place for fermentation and cell disruption
- Process Development Laboratories to accommodate small and pilot scale development work and engineering runs including capability for BSL-3 agents
- QC in-process testing and release capability
- Agile, flexible manufacturing based on single-use, skid-mounted process equipment in both pilot plant and manufacturing core to facilitate the rapid changeover of process configurations for different platform technologies within production suites
- The ability to accommodate up to four x 2,000 L bioreactors
- BSL-3 compliant facility design to allow development and manufacture up to BSL-3 conditions

Key areas of the ADM Facility depicted in Figure B-1 include:

Figure B-1. Key Areas of the ADM Facility



Area A:

- General Office
- Administration Spaces

Area B:

- CGMP QC Laboratories including:
  - Microbiology
  - Cell assay
  - Analytical Chemistry
  - Sample Management and Stability
  - BSL-3
- Development laboratories including:
  - Vector Development
  - BSL-3
  - Pilot Plant
- CGMP Viral Banking suite
- Cell Banking suite

Area C:

- CGMP Mfg. Core consisting of two CGMP, BSL-3 compliant manufacturing suites each consisting of:
  - Upstream Processing (USP) room
  - Downstream Processing (DSP) room

- Media and Buffer Preparation (MBP) room
- Weigh and dispense areas
- Washing and sterilizing areas to support CGMP manufacturing
- Shell Expansion Space for future build-out

Area D:

- Central Utility Plant

Area E:

- CGMP Warehouse

Upstream and Downstream Capabilities:

The ADM Facility can rapidly manufacture bulk product using a variety of biopharmaceutical processes and manufacturing technologies and platforms. The manufacturing core consists of two production suites that can be equipped, as needed, to accommodate various campaigns. In the typical set-up, each suite comprises one USP room and one DSP room. In addition, each suite is supported by a MBP room located between the USP and DSP rooms. However, to maintain flexibility, the four processing rooms can operate similarly, with possible assignment of the suites to either upstream or downstream operations as required to support necessary adjacencies for flexible manufacturing. The USP and DSP rooms are operated on a campaign basis for CGMP manufacturing with only one product in a room at a time.

The suites are designed as open floor with the ability to operate multiple pieces of process equipment simultaneously using primarily closed SUT to reduce or eliminate possibilities of cross contamination. Furthermore, most of the process equipment, including MBP systems are portable and thus removable and reconfigurable based on manufacturing and facility requirements. No process equipment is permanently fixed within the core manufacturing area.

All production rooms are BSL-3 capable and designed to promote unidirectional flow of personnel and materials. All BSL-3 waste materials are appropriately decontaminated in dedicated decontamination autoclaves located within each USP and DSP room, following established Standard Operating Procedures (SOPs).

Manufacturing Core Layout:

The CGMP manufacturing core consists of a series of open hall cleanrooms designed and constructed for biopharmaceutical manufacturing of bulk biologics. These cleanrooms are logically arranged with the proper adjacencies to allow predominately unidirectional flow of personnel, product, materials and wastes. Each processing suite of the CGMP manufacturing core consists of the following functional areas:

BSL-3 Commissioned USP Room with:

- ISO Class 8 (ISO 8) Clean Staging Room
- ISO 8 Gown-in Personnel Airlock (PAL) and Material Airlock (MAL)
- ISO 8 Processing Room equipped with decontamination autoclave
- ISO Class 7 (ISO 7) Gown-in Room
- ISO 7 Inoculum Preparation Room (with ISO Class 5 BSC)
- ISO 8 Degown PAL and MAL
- ISO 8 Exit Staging Room with shower out capabilities.

BSL-3 Commissioned DSP Room with:

- ISO 8 Clean Staging Room
- ISO 8 Gown-in PAL and MAL
- ISO 8 Processing Room equipped with decontamination autoclave
- ISO 7 Gown-in Room
- ISO 7 Bulk Filling Room (with ISO 5 BSC)

- ISO 8 Degown PAL and MAL
- ISO 8 Exit Staging Room with shower out capabilities.

MBP ISO 8 Room with:

- entry and exit airlocks

Process Support Rooms with:

- ISO 8 Rooms for glassware wash and sterilization capabilities

This design concept, with the MBP room between the USP and the DSP rooms is integral to the success of agile, flexible operations with SUS. The adjacency provides media/buffers/reagents to both rooms through liquid transfer ports. This greatly reduces traffic into and out of the processing areas, and greatly cuts down on buffer/media vessel congestion in the processing areas. Smaller quantities of media and buffer components can be transported manually via carts to the USP or DSP suites via the clean staging room and supply corridor, as needed, or make use of single-use Sartorius Biosafe rapid transfer ports, which accommodate aseptic tubing transfers. For space planning purposes, these suites have bench space for in-process analysis instrumentation, space for a portable CIP skid, consumables and tools carts, tubing welders and sealers, integrity testers, automation panels, biowaste kill system, and utility drops within the room.

TheADM Facility has a dedicated CGMP Cell Banking area for the creation of MCB and WCB and adedicated CGMP Viral Banking area for creation of viral stocks and infections agents. These ISO 7 cleanrooms are used on a campaign basis and may be used for other manufacturing activities as required. All open manipulations occur in an ISO 5 biosafety cabinet within the room. The Cell Banking and Viral Banking laboratories are located within the development area of the ADM Facility, in a monitored, secured and controlled environment, with access to the room through controlled airlocks.

Table B-1. ADM Facility Capabilities and Equipment

Facilities/Capabilities	Equipment
Manufacturing Suites	
Four dedicated ISO 8 CGMP/BSL-3 Process Rooms ISO 7 inoculum and bulk filling rooms with ISO 5 biosafety cabinets ISO 7 Cell and Viral Banking areas Clean utilities (WFI, Clean Steam, Process Gases) USP equipment to support microbial or cell culture processes DSP equipment Two ISO 8 Media and Buffer Suites w/ pass-through to adjacent Process Rooms Facility decontamination system (ClO_2) ISO 8 Support Rooms (Glassware Wash Supporting Quality Control Labs (BSL-3, analytical, cell assay and microbial labs)	▪ Decontamination and Sterilizing Autoclaves ▪ Single-Use Bioreactors of increasing scale-up to 500 L ▪ Stainless Steel Fermentors up to 150 L ▪ Single-Use Fermentor (50 L) ▪ Depth Filtration Systems ▪ Roller Bottle Incubators ▪ Large CO_2 Incubators for Cell Factory-Use ▪ Biosafety Cabinets ▪ CO_2 Incubators/Shaking Incubators ▪ Ultra-low freezers ▪ Refrigerators ▪ Cell Disruptors ▪ AKTA Ready Chromatography Systems ▪ TFF systems ▪ Viral Filtration Systems ▪ Bulk Filling Systems ▪ Filter and Bag Integrity Testers ▪ Continuous Centrifuges
Pilot Plant/R&D	
Vector Development and BSL-3 R&D labs	▪ Single-use Bioreactors of increasing scale-up to 200 L ▪ Stainless Steel Fermentors up to 150 L ▪ Single-use Fermentor (50 L)

Facilities/Capabilities	Equipment
Pilot Plant for process scale-up	▪ Roller Bottle Incubators ▪ Large CO_2 Incubators for Cell Factory Use ▪ Biosafety Cabinets ▪ Incubators ▪ Centrifuges ▪ TFF systems ▪ AKTA Avant and AKTA Ready chromatography systems ▪ Biosafety cabinets ▪ Refrigerators ▪ Ultra-low freezers ▪ Autoclaves
USP to support microbial or cell culture processes	
DSP	

The ADM Facility is designed to be a multi-product facility. The four processing rooms are capable of ClO2 decontamination, including associated inlet and outlet airlocks and the HVAC air-handling systems, each of which is individually zoned. Product changeover will be performed per SOP and validated decontamination procedures and will feature final room clearance by QA. Equipment is designed to be predominately single-use and will be capable of decontamination within the processing rooms prior to a new campaign. In addition to product changeover activities, the manufacturing core and support areas will be sanitized according to daily, weekly and monthly schedules using qualified and rotated cleaning agents and disinfectants. An environmental monitoring program is in place to monitor the effectiveness of the cleaning procedures and ensure continued performance of the cleaning program. CGMP manufacturing activities are also supported by the Logistics and Manufacturing Technical Services (MTS} Departments. The ADM Facility features a warehouse consisting of 22,375 f22 of controlled room temperature space. The warehouse is also equipped with a cold room storage area (2-8° C), -20° C and -80° C freezers.

Water for Injection System:
The Water for Injection (WFI) System includes equipment for generation, storage and distribution. The WFI generation system receives USP Purified Water from the central utilities plant and has been designed to condition incoming USP Purified Water into WFI using a multi-effect distillation process. The distilled WFI flows into a 9,000 L storage tank which provides capacity to manage peak demand and maximize generation equipment utilization. The WFI still output is designed for 300 gallons per hour (GPH). Combined with the 9,000 L storage tank the total generation capacity for WFI is approximately 33,500 L per day, which exceeds any envisioned surge scenario. To ensure microbial integrity, the contents of the WFI system is maintained hot (≥60°C to 85°C) by heating the water as it returns from the loop before returning to the storage tank. The WFI distribution loop is a continuous circuit that begins on the mezzanine and is distributed to the WFI Points of Use (POUs) in the preliminary sequence. There are 11 POUs for the Facility, IO in the CGMP core, including one to the manufacturing parts washer, and one in the Pilot Plant. Users requiring ambient WFI utilize a POU heat exchanger.

The WFI Loop instrumentation includes:

- Conductivity on the loop supply and return,
- Total Organic Carbon on the loop return,
- Temperature at the outlet of the loop-return heat exchanger, and
- Pressure on the loop return.

Clean Steam:
The clean steam system consists of a high purity clean steam generator and 316 L SS tubing distributed throughout the manufacturing core for sterilization and/or sanitization of equipment, parts and systems. The clean steam, when condensed, meets the requirements of USP for Purified Water. Additionally, the steam quality has been evaluated for superheating, dryness and non-condensable gasses per EN285.

Pharmaceutical Air and Clean Gases:
Carbon Dioxide, Oxygen, Clean Compressed Air, Nitrogen, and Instrument Air are distributed throughout the CGMP core for equipment use. Each processing space contains utility panels enabling connection of equipment to these gases. A second system is provided to supply the Cell and Viral Banking laboratories, Pilot Plant, and QC and Development laboratories.

Validation Program:
All direct impact utilities, process equipment and QC/Manufacturing laboratory instruments require qualification before use. MTS is responsible for tracking validation status, developing validation protocols, select protocol execution and writing validation summary reports. Third-party vendors are also used to supplement Ology Bio validation resources. QA Engineering provides oversight of the Ology Bio validation program and documentation. System and equipment requalification requirements are based on industry standards, regulatory requirements and periodic system quality evaluations. In addition, requalification may be performed if required by the Ology Bio change control process. Periodic certification of environmental systems and occasional recertification (after repair or relocation of affected equipment) is managed under the routine maintenance and calibration programs discussed above.

Change Control:
Ology Bio follows a systematic approach to manage proposed changes to products, systems, and processes. Changes are evaluated for their potential impact to product or system quality as well as impact to other systems and products. The need for re-verification and/or re-validation is determined and the associated data reviewed prior to implementation of the change. Changes to critical facilities, utilities systems and equipment are managed and documented using the MasterControl eQMS system following established Change Management Program and Change Control Process SOPs. Indirect and no-impact system changes and equipment changes prior to qualifications are documented as per the Engineering Change Management Procedure SOP.

APPENDIX C - QUALITY SYSTEMS

Quality Systems Overview:

Ology Bio's QS ensures compliance with CGMP Regulations, 21 CFR Part 211 and ICH Guidance for Good Manufacturing Practices for Active Pharmaceutical Ingredients -ICH Q7 and Biologics Regulations, 21 CFR Part 600. Ology Bio's Quality Management System (QMS) is ISO 9001 certified for the development, manufacture and distribution of biologics, pharmaceuticals and medical devices. Ology Bio QMS is comprehensive and provides processes and procedures necessary to perform all core QMS elements including:

- Management review
- Document management and control
- Deviations
- (CAPA)
- Change control
- Supplier selection and management
- Quality agreements
- Quality audits
- Employee training
- Calibration
- Customer complaint handling

The ADM Facility uses a combination of 21 CFR Part 11 compliant eQMS systems to manage the QMS processes. The selection of the eQMS systems was based on the degree to which each system met our performance expectations for each function, cost and the ease of implementation. The Quality Assurance (QA) Department reports to the Vice President of QA and is organized into functional areas providing comprehensive oversight of all QMS elements as listed below:

Table C-1. QA Core Functions

Quality Group	Core Function
QMS	▪ Management and administration of Quality System (QS) processes ▪ Document Management ▪ Document Control
QA Compliance	▪ Deviation/CAPA Management ▪ Change Control ▪ QA Compliance ▪ Batch Record Review ▪ Deviations/Root Cause Investigations ▪ Product Release ▪ Quality Audits ▪ Internal Audits ▪ Management Review ▪ Customer Complaints.
Supplier QA	▪ Supplier Selection and Approval ▪ Supplier Audits ▪ Quality Agreements ▪ Supplier Monitoring ▪ Incoming QC ▪ Raw Material Release
Quality Engineering	▪ Review and approval of facility and equipment validation plans, protocols and reports ▪ Review and approval of facility and equipment change control requests ▪ Review and approval of equipment and facility calibration and maintenance plans, procedures and exception reports

Quality Group	Core Function
	▪ Review and approval of process validation plans, protocols and reports ▪ Development, implementation and validation of electronic Quality Management Systems ▪ Review and approval of all manufacturing control system and CGMP software validation plans, protocols and reports ▪ Provide support for investigations ▪ Provide support for formal risk assessments

Quality Agreement:

Ology Bio will work with Blue Water to establish a mutually approved Quality Agreement that defines the quality requirements and responsibilities of each organization.

Quality Audit:

Ology Bio will support Blue Water quality audits of Ology Bio's systems and procedures, insofar as they relate to the service and control of Blue Water product. These audits may be performed on a periodic basis, not more than once per year, at times mutually agreed upon by Ology Bio and Blue Water. Ology Bio will provide Blue Water with monthly follow-ups on the status of audit observation commitments found in Blue Water annual audit or regulatory inspection, as they apply to Blue Water product.

Quality Software:

Quality uses a series of 21 CFR Part 11 compliant software solutions to manage Quality activities as shown in the table below.

Table C-2. QS Software Used at the ADM Facility

Software System	Function
MasterControl	Documents, training and risk; processes and audits; and calibration and maintenance
ComplianceWire	Training Management
QAD	Enterprise Resource Planning, Inventory Management and Control
LabVantage	Laboratory Information Management System (LIMS) – Sample Management and Stability
MODA	LIMS – Environmental and Utilities Monitoring
Software System	Function
MasterControl	Documents, training and risk; processes and audits; and calibration and maintenance
ComplianceWire	Training Management
QAD	Enterprise Resource Planning, Inventory Management and Control
LabVantage	Laboratory Information Management System (LIMS) – Sample Management and Stability
MODA	LIMS – Environmental and Utilities Monitoring

Quality Risk Management:

There are two levels of Quality Risk Management (QRM) as defined in the QRM Procedure:

1. Level I QRM encompasses the policies, procedures and practices used to manage risk through implementation of the QMS and management reviews
2. Level II QRM encompasses product-specific risk management activities employed during the product development and post-marketing phases.

- Acceptance Activities: Identified hazards and related risk control measures are considered when developing criteria for verification and acceptance activities.
- Critical Quality Attributes (COAs): CQAs are determined for products which are incorporated into product specifications.

Level I QRM occurs through the following activities:

- Auditing Program: The auditing program provides information to management concerning effective implementation of the QS. Risk management principles are used to determine the frequency and scope of audits, both internal and external, considering factors such as results of previous audits/inspections, the complexity and inherent risks of the related processes and the number and significance of quality defects.
- Change Control: Proposed changes to products and processes are evaluated for their potential impact to product quality. The need for re-verification and/or re-validation is determined and the associated data reviewed prior to implementation of the change.
- Deviations: Deviations are assessed and classified based on the risk posed by the deviation to process and product quality. The level of investigation, priority of corrective actions and level at which deviations are reviewed are commensurate with the criticality of the deviation. Approval of a deviation occurs when the QA approver has determined that the identified corrective actions have adequately mitigated the risks posed by the deviation.
- Corrective and Preventive Actions (CAPA): The CAPA process is used to reveal any previously unrecognized risks and to monitor the effectiveness of risk control measures. CAPA information is used to determine the effectiveness of risk management activities and to determine the actions to be taken to correct identified issues and prevent recurrence.
- Manufacturing, Measuring and Monitoring Equipment: Suitability of equipment, qualification requirements, maintenance schedules and calibration requirements are determined based on the risks associated with the process. SOPs are developed, reviewed and updated to reflect appropriate control measures.
- Production and Process Control: Risk control measures employed to address hazards posed by equipment, processes, work environment and personnel are part of the production and process control procedures. Production and post-production information on products are continually monitored and analyzed. This includes the rate of non-conformities, the rate of rework, scrap and yield. This information is used to confirm the adequacy and completeness of risk controls.
- Critical Process Parameter (CCPs): Processes are evaluated to determine those CPPs which can affect CQAs. Once CPPs are identified, critical control points are identified, and in-process controls are implemented to mitigate risks from these process steps.
- Purchasing Controls: Purchasing requirements are used to control risks associated with suppliers. The criteria for selection, evaluation, and re-evaluation of suppliers are based on the level of risk associated with the products and services provided.
- Traceability: Risk management principles in conjunction with regulatory requirements are used to establish the criteria for traceability. All components, materials, and work conditions that could potentially cause a product not to satisfy its specified requirements are considered in establishing traceability criteria.
- Work Environment and Personnel: If the work environment or personnel are determined to pose a risk to products or processes, risk control measures are defined and implemented. The training process is used to ensure that personnel understand the implementation of risk control measures and the significance of their work with respect to product quality.
- Supplier Management: Potential suppliers are identified and placed into risk categories based on the impact of material or services on CGMP product and processes. Qualification of suppliers may include site audits and/or supplier quality survey based on the risk category.
- Concurrent Multiproduct Manufacturing: A process to evaluate risk associated for selection of new project, proposal development and introduction of samples, products or manufacturing campaigns has been developed. This process assesses the risk and identifies requirements for introducing and handling of new biologic, pharmaceutical or medical device sample, material, product or campaign into the ADM Facility. This process is intended to ensure client product quality and patient safety is maintained through reducing the risk of potential contamination and/or cross-contamination while preserving personnel and environmental safety conditions.

Level II QRM also includes design and process risks which are evaluated using tools such as Failure Modes Effects and Analyses. This process includes a thorough breakdown of risks, followed by risk assessment and risk control in accordance with ICH guideline Q9 - QRM. Risk assessment includes analysis and evaluation consisting of potential cause, severity, detection, occurrence, and current controls. Risk control is the mitigation strategy for the identified risk. The ADM Facility is incorporating the principles of QRM described in ICH Q9 into its QMS. The Facility has built the QRM elements into its QS processes including:

- Risk Identification
- Risk Assessment
- Risk Reduction
- Risk Acceptance

The ADM Facility integrates these elements into its QS processes as demonstrated through quality records of impact assessments for deviations, CAPA, and change control, and validation efforts which are utilized to make risk-based decisions commensurate with the consequences of the risk to the safety of the patient.

Quality Control:

The ADM Facility has developed robust Quality Control (QC) systems and policies based on CGMP. Our team will provide Blue Water with the highest quality products and services. QC is governed by the QS, which are applicable to the entire Facility site to ensure alignment to the site Quality Philosophy. In addition, QC is controlled by a series of SOPs which specifically apply to operations that are unique to QC laboratories.

The Senior Director of QC manages the QC Department and is responsible for all environmental and utilities monitoring, in-process, release and stability test programs and assuring that all testing is performed in accordance with applicable CGMP regulations. Key responsibilities of the QC Department include:

- Control, distribution and disposal of product release, in-process and raw material test samples
- Qualification/validation of analytical methods, systems and equipment
- Performing QC release testing for raw materials, in-process control, Drug Substance, and Drug Product
- Reporting and approval of release and in-process test results
- Managing the stability test program
- Performing stability testing and preparing interim and final stability reports
- Participate in the establishment of specifications
- Performing/trending environmental and utilities monitoring testing
- Support qualification and manage analytical subcontractors

The QC Department consists of the four functions outlined in the table below.

Table C-3. QC Core Function

Quality Group	Core Function
Sample Control/Stability	● Receive, track and distribute test samples ● Manage the scheduling of stability sample testing ● Maintain accurate invento of sam Jes
QC Microbiology	● Perform microbiological testing on finished product, bulk API and raw materials ● Responsible for the environmental and utilities monitoring program including collecting and testing samples and trending results ● Disinfectant efficacy
QC Analytical Chemistry	● Perform physicochemical testing on finished product, bulk API and raw materials
QC Cell Assay	● Perform immunoassays, cell-based assays and virology testing in support of in process and release ● Oversee testing for adventitious agents and animal testing performed for product release

Equipment Qualification, Calibration and Maintenance:

The equipment in the QC laboratory is covered by the site-wide Qualification and Equipment Maintenance Programs to ensure that a fully CGMP-compliant system across the site is qualified and included in the calibration and preventive maintenance programs. In addition, a QC equipment program was implemented to address QC-specific instrument procedures. Operation and Maintenance (O&M) procedures are implemented for all equipment and use of equipment is recorded in log books. Management of QC equipment calibration schedules are accomplished through Ology Bio's Calibration Program which includes procedures to ensure that equipment that is not appropriately qualified and calibrated is tagged and taken out of service. Further, documentation procedures ensure that all data can be traced to the equipment on which it was generated, so that data from malfunctioning equipment can be reliably identified.

Validation and Qualification:

The quality of the data from the QC laboratory relies on robust methods which are validated according to ICH and other applicable guidelines. The competent and well-trained staff ensures the development of methods based on scientifically sound principles which are appropriate for the product. Method development reports are prepared for all methods developed at the ADM Facility. Compendial methods are verified at the Facility QC laboratories as required by USP <1226> and other compendia! chapters. Non-compendial methods are subjected to phase appropriate qualification or validation according to applicable guidance.

Technical Capabilities:

QC serves as the raw material, in-process, and batch release testing and stability laboratories for products developed and/or manufactured at the ADM Facility or transferred to ADM Facility for testing. Therefore, a wide range of products need to be handled by QC. These could be well characterized vaccines generated by recombinant methods or complex products such as live vaccine products or polysaccharide conjugated products which are not well characterized.

The adherence to harmonized and CGMP procedures is ensured at the facility QC laboratory by implementation of effective SOPs. These SOPs cover areas such as laboratory investigations, general procedures for handling reagents and reference standards, operation and maintenance of equipment, the Stability Program, method validation, sample management and personnel training.

Where the methods or expertise are not available in-house, the testing is out-sourced to reliable and approved laboratories. For example, all required animal testing and adventitious agent testing are currently out-sourced. Methods that are expected to be only used for product/process, development, product characterization or Drug Substance, such as Surface Plasmon Resonance for binding studies, Capillary Electrophoresis, Analytical Ultra Centrifugation, LC-MS/MS, LC-QTOF-MS, Higher Order Analysis to include Circular Dichroisrn, Nano Differential Scanning Calorimetry and Microflow Imaging are not currently planned to be implemented in the QC Department.

Contract testing organizations used for out-sourced testing are assessed and approved through supplier approval program. Method development, transfer and technical oversight is provided by QC functional area management. Sample management and distribution as well as communication of results are managed by the QC Sample Control Department.

Data Management:

Information security at Ology Bio is practiced at all levels in the organization and on all hardware and software. A combination of on premise servers and cloud services are utilized for information processing. Information security of on premise systems and cloud systems is assessed for each independent system. Appropriate controls are in place for workstations (laptops, desktops, thin clients), servers, and network appliances. Leveraging industry best practices and National Institute of Standards and Technology (NIST) guidance documentation, Ology Bio examines information security in six domains: Physical, Hardware, Software, Compliance and Procedural, Personnel, Logical. These domains address topics such as identity verification, access controls, principle of least privilege, physical security, antivirus, encryption, and various regulatory compliances.

Security:

Ology Bio utilizes a layered approach to securing information. Detailed information on each security layer is further described below.

1. Physical:
   - Access Control - The building has a proximity card access control system. Only employees and qualified vendors are allowed access to the building. The Information Technology (IT) closets also separately access controlled with limited individuals having access. There is a single entrance monitored by video and a security guard.
   - Security- The building has 24-hour on-site security guards. At a minimum, there are two guards present.
     One monitors exterior perimeter, while the second monitors the interior. There is also constant video surveillance covering most of the building. The video software captures and records all motion events across all interior and exterior cameras.
   - Fire Detection - The Facility has a dry-agent fire suppression system in all IT rooms to prevent damage to equipment. This system is monitored by the security operations center internally.
   - Environmental Monitoring - The IT rooms are constantly monitored for temperature and humidity. In the event the air conditioner fails, and the room becomes too hot, the system immediately alerts the internal security office and IT staff.

2. Hardware:
   - Firewall, Intrusion Detection System (IDS), Intrusion Prevention System (IPS) - A redundant pair of Cisco ASAs is used as a firewall, IDS, and IPS. Security policies are only modified by the IT Department. In the event of a data breach, local authorities are contacted.
   - Uninterruptable Power Supply- All servers and network equipment are run on the building's UPS system. In the event of a power loss, the backup diesel generator activates to relieve the batteries.
   - Redundant Hard Drives - All servers and storage utilize some version of Redundant Array of Independent Disks. This ensures that if a hard disk fails, the system will continue to operate normally until the disk is replaced.
   - Off-Site Backups - A hardware backup appliance is used to backup data. The backup appliance stores a local copy of data and has the ability to tum on a virtual machine to mimic a server in case of catastrophic failure. This appliance also uploads encrypted and compressed data continuously to an off site data center.
   - Disaster Recovery - Disaster recovery plans are in place in the event of catastrophic system failures. These plans will integrate with the business continuity plans.

3. Software:
   - End-Point Antivirus - All workstations and servers run a local anti-virus software. Virus definitions are updated daily. Only system administrators can stop the antivirus from running.
   - Active Directory Security Policies - Various active directory security policies are in place to ensure data integrity. Active policies are based on government guidelines, including Federal Desktop Core Configuration/U.S. Government Configuration Baseline and Federal Information Processing Standards.
   - Activity Logs - Active directory audits user logins and access attempts. These logs can be reviewed to determine if sensitive data is being accessed by unauthorized individuals.
   - FDA 21 CFR Part 11 - Often called ''Part 11 Compliance" is a special set of rules enabled in certain applications to enable the use of electronic signatures. Electronic signatures are utilized in applications such as the Enterprise Resources Planning software, Document Management Software, and Quality Management Software.

- Software Patches and Updates - Software vendors publish security updates frequently to ensure the security of their products. These patches are enumerated by the IT Department, tested in a segregated network, and then pushed to appropriate users and computers.

4. Compliance and Procedural:
   - Regulatory Compliance - Various regulatory requirements require different levels of security. Needs of all regulatory bodies are reviewed and efforts made internally to meet them all.
   - Change Control - A change control system is in place to prevent changing of network configurations. Configurations are locked by the IT Department, and changes are not made until the proper change control process, including impact assessments, is followed.
   - SOPs - Various SOPs are in place governing the operation and maintenance of applications, network, and computer systems. All IT staff members are trained on appropriate SOPs before being given access.
   - End-User Training - Training is provided to end-users before being granted access to the system. Training is also provided for new systems that may be launched. Records of all training are kept with each employee's file.

5. Personnel:
   - Each new hire must complete an 19 form, present sufficient identification to verify identity, and have a background check performed. Depending on the position in the company, multiple, in-depth backgrounds checks may be run.

6. Logical:
   - A combination of Mandatory Access control and Discretionary Access Control is used to protect data confidentiality.
   - The principle ofleast privilege is used when giving access to information systems.
   - Privileged system accounts (e.g. administrator/root) are highly controlled and only used for appropriate purposes.
   - Encryption is applied where required. TLS is implemented for sensitive email communication and on several internal software systems. Laptops and other mobile devices have their internal storage (e.g. hard drives) encrypted.

APPENDIX D - PROGRAM AND RISK MANAGEMENT

Our commitment to client satisfaction and delivering high-quality work are our primary objectives. To achieve these objectives, experienced technical and program management staff will lead the Ology Bio efforts, oversee subcontractors and represent us on an Integrated Product Team (IPT) established with Blue Water. A Program Management Plan (PMP) will be generated to coordinate all aspects of the project plan. The elements of the PMP will contain, at a minimum, the following:

- Project Charter - Establishes a collective understanding of the goals of the project as well as its governing ideals particularly regarding decision making and issue resolution.
- Communication Plan - The Project Manager (PM) is primarily responsible for project communication. The communication plan includes details on how project information will be disseminated to team members (internal weekly meetings, weekly client meetings)
- Integrated Master Schedule (IMS) - A detailed IMS using Microsoft Project will include all activities, deliverables and Go/No-Go decisions. The IMS will be updated and provided to Blue Water by the l0th of each month.
- Work Breakdown Structure (WBS)- A WBS will be generated that aligns with the scope and IMS.
- Cost Management/Budget Plan -A time-phase cost management/budget plan will detail the forecasted milestones and budget. The plan is updated monthly and provided to Blue Water by the 10th of each month.

Project Charter:

The project charter establishes a collective understanding of the goals of the project as well as its governing ideals particularly regarding decision making and issue resolution. It provides formal authorization for the project and provides the PM with the authority to apply organizational resources to conduct project activities. The charter references the purpose and goals of the project, project scope, success criteria and specifies the team members from each contributing organization along with each person's role on the project. It also provides a description of the product along with key milestones, project risks, constraints and assumptions.

Product Development Teams:

The core members of the PDT include at a minimum the Principal Investigator (Pl), the PM, and the Finance Manager. The PM is ultimately responsible for overall project management and communication, tracking performance, monitoring and reporting on project status and progress and facilitating discussions on modifications to project requirements and timelines for the overall project. This includes management of work performed internally and by subcontractors. The PM oversees the project budget, schedule, work scope and project risk planning and management. Budget oversight is performed in close communication with the Financial Manager, who is ultimately responsible for financial management of the program, and who provides financial reporting to the PM monthly. The core team also includes the Pl, who serves as the scientific lead and communicates continuously and comprehensively with the PM and all technical support areas to ensure a technically sound program.

Given the key role played by Ology Bio and the various subcontractors on this effort, our project teams have learned that a high-level of subcontractor oversight leads to a high-quality product. Ology Bio uses robust processes and practices as well as appropriate point of contacts for the project within both organizations to ensure success of the overall requirements management, project planning, project tracking and project oversight along with the coordination of QA and Change Management.

The PM maintains a continuous check on the overall program scope, schedule and budget as well as individual subcontractor schedules and budgets to ensure contract compliance. The PM carefully monitors progress via continual communication with the PDT and by verifying the activity accomplishment against the IMS. The PM schedules regular (weekly, bi-weekly or monthly as appropriate) team meetings to track open action items and trace them to closure. The PI also ensures that each technical member of the team is meeting all technical requirements stated in the contract. Interaction between the PM and the PI is of paramount importance and occurs continuously. Each one updates the other with the status of items in their respective areas over the entire course of the project. When changes must be made to the schedule due to scientific/technical issues, they coordinate revisions, risks, and costs together. Both also continuously assess risks and establish mitigations to ensure success of the project.

Functional Members of the PDT:
Highly specialized functional representatives will be chosen to support each PDT based on the skills needed to execute the work scope requirements. This ensures that the PDT is fully capable of effectively planning a strategy to achieve licensure based on the expertise possessed by members in all necessary product development areas. The PDT is the primary operational entity charged with successful start-up, implementation and completion/ closeout of each project in alignment with the goals of the contract.

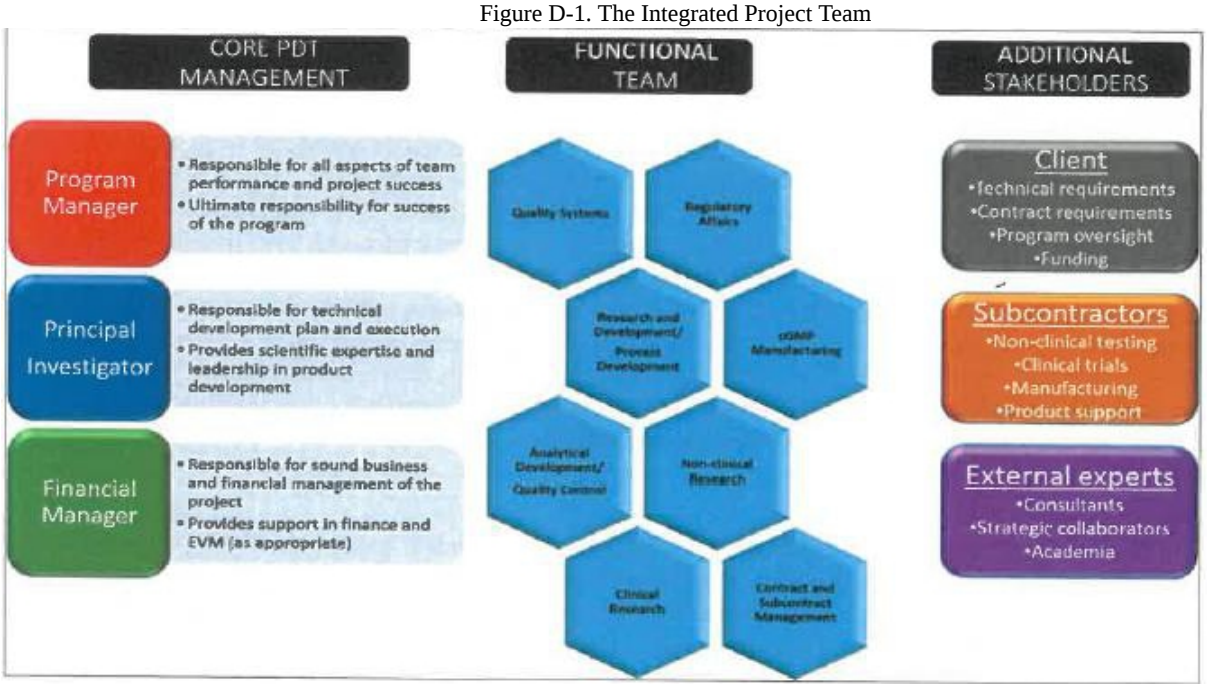
Each PDT member has two reporting pathways in our matrixed management structure. Members report to both the functional department head and the PDT. The effectiveness of a matrixed cross-functional team is dependent on continual structured communication between the PDT members and senior management. The team uses this customized chain of command to identify, elevate and propose solutions to critical issues impacting contract cost, schedule and scope. The PDT's success hinges on the ability to interpret and react quickly to new technical data, changes in FDA directives and/or business issues. Use of the cross-functional team structure, along with established communication pathways and regular access to senior management ensures that the team operates effectively.

Our senior management supports the mission of the PDT leadership by providing appropriate resources and guidance to maximize success. Management also ensures that the teams do not function in isolation of each other; that is, information flows between PDTs to guarantee that lessons learned, and best practices are equally disseminated not only as a form of risk management, but also as a means of continual process improvement.

The Integrated Project Team:
To maximize efficiency and to ensure that all stakeholders in a program are fully represented, Ology Bio regularly employs an IPT paradigm for oversight of projects. Establishment of the IPT is intended to facilitate effective communications for generating broad awareness of project status and for decision making when the PDT requires guidance. The IPT will help to integrate all organizations that have a stake in the performance of the project so that key decisions affecting the project/product are made with collective awareness and buy-in. The IPT includes the PDT as well as members from Blue Water and any necessary technical resources that may be employed on an ad hoc basis (consultants, academic investigators, etc.). In addition, subcontractors to the PDT may also be included in the IPT, depending on the project scope (complexity) and the desires of the stakeholders.

The team will provide technical, administrative and analytical support to the IPT as required. This will include, but not be limited to, scheduling the meetings, creation of meeting agendas, meeting minutes, working notes, summaries, reports, analyses and briefing materials as required. The IPT meetings will allow for sharing of specific information regarding the project timeline and deliverables status. The IPT structure and composition is illustrated in **Figure D-1**.

Figure D-1. The Integrated Project Team



Project Initiation:

The project initiation phase requires a comprehensive review of the project scope and budget, official assignment of the PDT, verification and finalization of the project IMS, IPT and project milestones and deliverables. In addition, project stakeholders and stakeholder interfaces are determined, which will lead to subsequent creation of a Project Charter. A project kick-off meeting will be scheduled within two weeks of signing, which will set the tone for the project and provide the team with the details necessary to begin conducting work appropriately, as per the terms of the contract. Specific project initiation activities are detailed below.

Integrated Master Schedule (IMS) Development:

The IMS comprises the processes and core activities necessary for successful project execution and completion and is the primary tool used by the PM to track and manage contract and project activities. Each activity in the IMS is assigned a WBS number to match the outline of project work. The schedule includes a separate line item for each required activity along with planned start and finish dates. The start date for each activity or task is driven by an appropriate linkage to a predecessor task or tasks. The finish dates are driven by the duration of each task. The IMS cannot contain constraints, which will lead to an inaccurate critical path. The initial IMS for a project is established by members of the PDT and will then be negotiated with Blue Water during the proposal negotiation phase.

A more detailed schedule will be created after contract award. Once work begins, portions of our subcontractor’s schedules are also inserted into the IMS so their activities will be added to the plan and tracked. The IMS includes the approved baseline schedule and actual schedule as well as a column to indicate percentage completion for each task. Schedules are updated at least monthly to show task progress and schedule slippage. The updated IMS will be provided in monthly reports to Blue Water.

Meeting Management:

Post-Award Contract Initiation (Kick-Oft) Meeting:
A post-award contract kick-off meeting will be scheduled within 14 calendar days following the effective date of contract award with all key contract stakeholders. The kick-off meeting is conducted to establish a common purpose among stakeholders and to provide for a clear understanding of the scope of the project, the schedule for key activities/milestones, the team roster and individual responsibilities, appropriate communication pathways and the general administration of the project. The post award contract kick-off meeting will be a one day meeting. The location for the meeting will be mutually determined. To support the post award contract kick off meeting, Ology Bio will provide read-ahead materials, presentations, relevant documents, and an agenda. This meeting will be attended by Ology Bio key personnel, designated Subject Matter Experts (SMEs), and investigator representatives. The PM will work with Blue Water to determine timing and location for this meeting. PM will provide a meeting report within 7 calendar days after conduct of the meeting. This report will include action items and due dates, any presentation materials as well as summaries of the discussions held.

PDT Meetings:
The PDT assigned to manage the contract will meet on a weekly schedule or as needed. These meetings will be focused on updates to critical path activities and issue resolution. The PM will facilitate these meetings and will be responsible for capturing the meeting minutes and for their distribution to the rest of the PDT. The PM will also be responsible for capturing action items and for ensuring that assigned PDT members complete them on time.

IPT Meetings:
The PM will facilitate IPT meetings which will suffice as Progress Review Meetings to be attended by the essential members of the PDT, and Blue Water's staff to provide updates on contract performance. The PM will provide agendas for these meetings to all IPT members in advance. The PM will capture minutes from all IPT teleconferences and will provide minutes within five business days.

Ad Hoc Meetings:
Ad hoc meetings will be held as necessary, upon team member or Client request, to discuss issues as they arise. Contract-related information and updates will be provided to Blue Water upon request. Minutes from these meetings will also be provided as described above for IPT meeting minutes.

Product-Specific Risk Management Plan:
The development of any product carries with it inherent risks that must be considered as part of the overall Program Management Plan. The Ology Bio Project Risk and Opportunity Management Procedure governs how project risk management is conducted. The Ology Bio team views risk management as a continuous project lifecycle activity and an integral and vital component of project management. Appropriate risk planning and analysis will enable the PDT to think toward tomorrow, identify uncertainties, and anticipate potential outcomes, while managing project resources and activities. Risk management, as performed by our team, includes the identification, assessment, and management of areas that could affect our ability to achieve overall program objectives within the defined quality, cost, and schedule criteria Assessing, mitigating, monitoring, and communicating risk events is a Ology Bio best practice conducted regularly on all our programs to enhance our ability to eliminate or control project inefficiencies.

The risk management methodology and processes that will be routinely utilized throughout the lifecycle of the project to include: Risk Identification, Risk Analysis and Quantification, Risk Response Development, Risk Mitigation, Risk Monitoring, and Risk Response Control.

Risks, Risk Mitigation and Opportunities Identified:

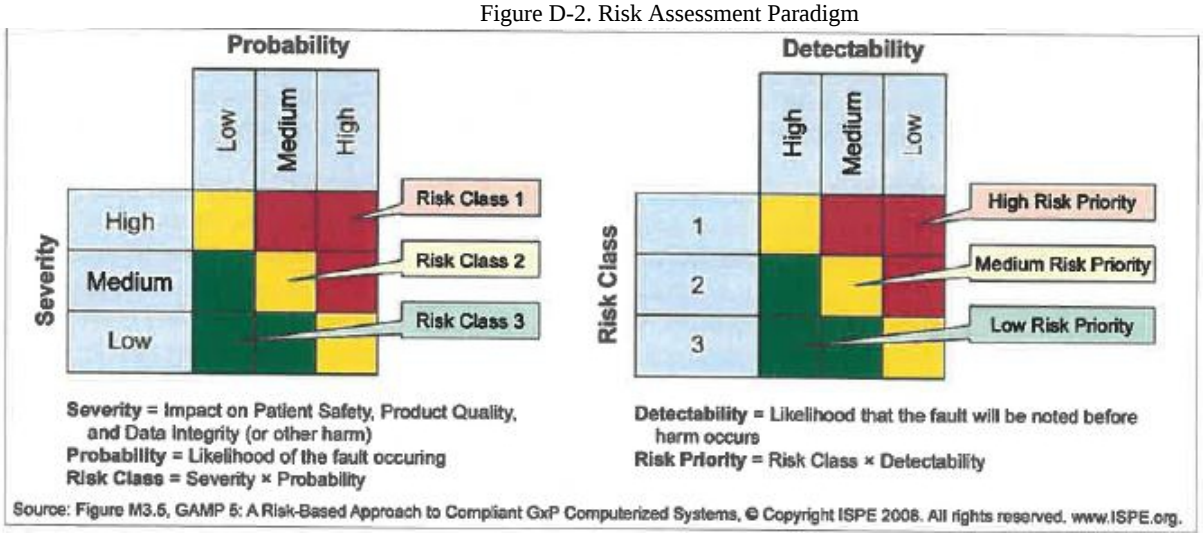
The PDT uses a well-defined, systematic, and iterative process to identify, assess, mitigate, and respond to areas that could prevent us from meeting project objectives within the defined requirements. A robust risk management program is implemented throughout the lifecycle of the program. At a very high level, the methodology and processes that will be routinely utilized include: Risk Identification, Risk Assessment and Quantification, Risk Response Development, and Risk Response Control.

It is important to note that we would prioritize the risks upon award to ensure that the focus is placed on the highest priority risks and that appropriate resources are being applied to those first. It also bears mentioning that the preliminary Risk Assessment provided is not a fully comprehensive list of potential risks, and that it is created to identify certain high-level risks experienced on other programs and to be sure that all pertinent functional areas of the program are represented. The Risk Plan will be updated regularly, and continual re-assessment of existing risks and their ratings will be required, to include the identification of new risks as work progresses.

Risk Identification:
Under the direction of the PM, the cross-functional PDT routinely uses proven risk management techniques to identify and assess all risk events throughout the lifecycle of the project. Planning tools such as project requirements, product specifications, the technical approach, costs and schedule baselines, product historical data, subcontractor insight, and regulatory agency requirements are all key inputs to risk identification. As development progresses, complementary techniques to identify risks are part of other program activities such routine status meetings and program reviews.

Risk Assessment and Quantification:
The PDT will evaluate the probability of occurrence and the potential impacts of each risk event on the project's performance, schedule, and cost objectives using numeric definitions on a scale of 1-5. The risk values will then be placed in a Risk Severity Matrix (RSM) which defines the risk as low (green), medium (yellow), or high (red). Probability is based on understanding the requirements and performance goals of each task order (TO) and is determined by quantifying the likelihood of occurrence. The overall likelihood that an event will occur is estimated by combining data and the knowledge and experience of SMEs. The Risk Assessment Paradigm that we employed is illustrated in **Figure D-2** below.

Figure D-2. Risk Assessment Paradigm



During risk analysis, the impact of a risk event occurring must be accurately predicted. Four primary areas are assessed to determine how severe the impact is likely to be:

1. **Impact on the Technical Performance:** The most severe impact on a program is the impact on the product performance. The impact on the performance of the product is assessed based on how the risk will impact our ability to meet the requirements as defined in the contract.

2. **Impact on the Activity Schedule:** A risk event will ordinarily affect the time required to complete the activity affected. Any delay that a risk will cause to the project schedule is assessed based on lessons that Ology Bio has learned through other projects and the knowledge of the PDT. When assessing the impact to the project schedule, the time required for quality investigations and corrective/preventive actions are also taken into consideration.

3. **Impact on the Program Schedule:** When a risk event impacts the critical path, there is real potential for delays to the overall project schedule. This impact is assessed by considering whether the risk itself is on the critical path or whether it impacts other activities that are, and then estimating any additional time that would be required to recover from the risk event.

4. **Impact on the Budgeted Cost of the Program:** The PDT will calculate cost impact using the costs associated with the activities related to the risk event by determining the number of additional full-time equivalents required to complete work that would need to be repeated or new work that would be required if the risk event occurred as well as supplementary non-labor costs (materials, equipment, etc.). If the risk event is anticipated to push critical path an additional cost impact will be calculated based on an estimated project cost per day and delay period. Sequential to the risk cost impact, a risk-adjusted value is also determined. This is a budgeting tool that weighs the probability of the risk to determine the amount of money that should be put into the risk reserve as a precautionary measure.

Once a risk event is assessed, the PDT will determine the overall severity or level of a risk by multiplying the risk probability by the combination of the risk impacts. These calculations allow for prioritization of the risk events on the RSM and a determination of which risk events justify the continued expenditure of time and effort on mitigation planning and execution.

Risk Response Development:
The key to risk mitigation is applying the appropriate action at the proper time. The RSM represents the magnitude of the risk and is used to prioritize and select among alternative mitigation strategies. A feasible risk mitigation strategy is technically sound, costs less than the cost impact if the risk event were to occur, does not create unacceptable delays, and does not adversely affect the ability to meet performance or quality requirements. Risk mitigation activities help reduce or control the probability and/or impact of a risk event.

When risks are identified, and analyzed, it sometimes becomes evident that a contingency plan must also be developed to prepare for the occurrence of an anticipated, problematic event. Using the RSM, the PDT will identify risks that are of a high enough probability and/or impact to warrant contingency planning. In these cases, a preliminary contingency plan, containing a rudimentary description of actions for responding to an undesirable occurrence will be developed. A triggering event, which may be a date, a set of conditions, or a combination thereof, will be used to identify the conditions under which the contingency plan is to be further developed and activated.

Risk Response Control:
The selected mitigation strategies will be converted to a set of specific actions, and responsible parties assigned to each. The PM will communicate regularly with the rest of the PDT to obtain mitigation statuses and will call meetings to allow the team to discuss the effectiveness of the mitigation and reassess risk(s) as needed. In some cases, the team may determine that it is appropriate to further develop the contingency plan at that time.

Risk communication is at the heart of risk tracking and control. Risks will be discussed at regular project status meetings, and meetings dedicated to risk planning. Anytime new activities are planned, risk is a routine consideration. The PM will present risk status and proposed plans for risk mitigation and contingency at all product reviews throughout the lifecycle of the project, fully briefing Ology Bio management on all serious risks, and ensuring that they are aware of those risks requiring external mitigation support.

Operational Risk Management:

New projects/programs transferred into the ADM Facility are reviewed and a risk assessment is conducted in accordance with established SOPs. This assessment at a minimum evaluates safety, occupational health, disinfectant efficacy, cleaning validations, biowaste kill validations, segregation concept as well as personnel, material and waste flows. Operational and safety hazards are assessed by the Biosafety Officer. Contamination and cross contamination risks are assessed by QA. The outcome of these assessments is determined by the Institutional Biosafety Committee.

Change Management Plan (CMP):

The Ology Bio Team understands that a CMP is needed to address project scope changes. This plan is generated according to our existing SOP and a Change Request Form, crafted for use on the project based on client input, to ensure all proposed changes to authorized scope are reviewed and approved in advance. This will include changes to the contract or to any subcontracted efforts. The CMP also ensures all changes are evaluated appropriately and coordinated across the entire project and all stakeholders are notified of approved changes. The plan will address how the project ensures changes are beneficial, determine how the change occur and allows for management of the changes as they are implemented. Records of changes are maintained in the Product History File and documented in the project Decision Log. This is of utmost importance when there are a number of changes required on a given project, so the PDT understands what is in scope vs. out of scope.

The change management process for a prime contract and for subcontracted efforts includes the same basic steps, as follows:

1. Submission of a written change request identifying and defining the proposed change;
2. Reason for the change;
3. Evaluation of the proposed change and its necessity;
4. Evaluation of any risks and/or impacts (cost, schedule, scope and/or quality) associated with the change;
5. Approval or rejection of the requested change in writing;
6. Modification of project plans to reflect the approved change;
7. Communication of the change to all affected parties.

The individuals required for review and approval of proposed changes are defined within the Change Control Plan. This plan includes procedures for handling emergency changes requiring approval and initiated without benefit of a full review.

Deliverables Acceptance Plan:

A Deliverables Acceptance Plan will be created according to our existing model which includes a Deliverables Acceptance Form template for use. The objective of the Deliverables Acceptance Plan is to provide a consistent format for describing project deliverables and specifying the criteria for their acceptance in an appropriate amount of detail to allow for the straightforward determination of acceptability. The plan will include the individuals responsible for review and acceptance and their roles in the acceptance management process. Objectives of the plan includes ensuring the requirements and expectations of the project deliverables are clear to the PDT and that acceptance is obtained in a timely manner to prevent undue delays. The Deliverables Acceptance Plan document is intended for use during the execution and close-out phases of the project, and as such is used during each phase as deliverables are submitted to Blue Water, at the end of the project, or both. The plan begins with identification, documentation and agreement by all key stakeholders with the quality requirements of each project deliverable, to include required timing for delivery. After the deliverable review process, signature by the documented review authorities indicates that the deliverable:

- Meets the specification;
- Has no significant unresolved issues;
- Meets the acceptance criteria;
- Is ready for release either as a baseline for subsequent work or as a stand-alone deliverable.

Reporting:

Monthly Reports:
Ology Bio will provide Monthly Technical Progress Reports, as required, to include an Executive Summary and updates on activities initiated and/or completed during the reporting period as well as activities planned for future reporting periods. An overall progress, management and administrative update, and technical progress section will be provided. The technical section will include subtask updates such as cell banking, manufacturing processes, analytical assay development, and manufacturing run status. Updated financial information and an updated IMS with percentage completion of required activities, and milestones will be included in the monthly reports. The monthly report will be provided by the 10111 of each month.

Final and Draft Reports:
Ology Bio will provide documents through the course of contract execution, including, but not limited to, the following:

- Technical and Scientific Development Reports
- Assay SOPs and Qualification Reports
- Master Production Records
- Executed Batch Records
- Certificates of Analysis
- Campaign Summary Report
- Stability Reports
- Microsoft Word documents in CTD format to support regulatory filings

Ology Bio will submit a draft report summarizing all the work performed on the contract to cover the full contract scope and period of performance. The report will describe the salient results achieved in the work conducted. The draft will be submitted for review within 30 days following completion of the study unless otherwise agreed to in the IMS and will be edited into the final report after comments have been received. Ology Bio assumes that the first draft will be due to Blue Water at least 30 calendar days prior to completion of the last contracted activity, one round of review and a two-week turnaround for receipt of comments. The final report will be submitted within 7 calendar days after receipt of client comments on the draft report.

Subcontract Management:

Ology Bio uses acquisition planning as an integral part of our proposal efforts to identify subcontractors that best meet the needs and scope of work for our clients. Ology Bio has an approved purchasing system and follows Procurement SOPs to facilitate fair competition. The technical team provides a detailed Statement of Work (SOW) and list of companies to the Procurement Department personnel. Procurement prepares the Request for Proposal containing the SOW, Standard Terms and Conditions, Vendor Qualification form and, if applicable, a Quality Vendor Application.

Upon receiving the subcontractor proposals, the Procurement team will review them for compliance and then distribute to the technical team. The technical team will evaluate each bidder's technical approach; personnel and project management; facility and resources; cost/price; schedule and quality assurance, and then completes a technical evaluation form. Once the technical evaluation is completed, Procurement conducts a best value review, which includes a source analysis; performance evaluation; a cost/price analysis of the bids provided and an assessment of the bid process.

Our project teams have learned that a high-level of subcontractor oversight leads to a high-quality product. The PM is ultimately responsible for management of work performed by the subcontractor. Once work begins, portions of our subcontractor's schedules are inserted into the IMS so their activities will be added to the plan and tracked. The PM maintains a continuous check on the individual subcontractor schedules and budgets to ensure contract compliance.

Subcontractor Risk Management:
Each supplier providing services or materials to Ology Bio goes through a risk assessment process. Ology Bio puts suppliers into categories based on the potential impact the service or material provided will have on product quality or regulatory compliance. Suppliers with the greatest potential impact are placed in the highest risk classification (i.e., subcontractors conducting CGMP or GLP services). Quality Agreements are established for all suppliers in this classification that defines the quality requirements and responsibilities of each organization.

APPENDIX E - RELEVANT COMPANY EXPERIENCE

From its beginnings, Ology Bio's growth was fueled through grants and contracts from both industry and several U.S. Government (USG) agencies. Today, Ology Bio has grown to nearly 200 employees located in three U.S. locations.

On March 30, 2013, The Department of Defense (DoD) awarded Ology Bio and its team of partners and collaborators, a contract to provide all the core services necessary to establish a Medical Countermeasures Advanced Development and Manufacturing (MCM ADM) Facility dedicated to meet the specific needs of the DoD. The 10-year, $400+ million contract had a base period goal for the construction of an 180,000 ft^2, state of-the-art, BSL-3, single-use facility that the Ology Bio now occupies and operates.

On September 25, 2013, The Biomedical Advanced Research and Development Authority, within the Office of the Assistant Secretary for Preparedness and Response in the U.S. Department of Health and Human Services established a fill and finish network. Ology Bio was awarded a prime contract to partner with a pandemic influenza vaccine manufacturer to transfer the fill and finish contract manufacturers technology into its existing facilities to provide surge capacity for drug shortage and emergency pandemic response products (e.g., anti Ebola monoclonal antibody, pandemic influenza vaccine). Ology Bio's expanded fill and finish network can provide these core services for manufacturers of drugs and vaccines intended to treat and protect public health against chemical, biological, radiological and nuclear threats.

AS WITNESS this agreement has been signed by the duly authorised representatives of the parties.

SIGNED for and on behalf of
OXFORD UNIVERSITY INNOVATION LIMITED:

Name: DR PAUL ASHLEY
HEAD OF TECHNOLOGY TRANSFER
LIFE SCIENCES
OXFORD UNIVERSITY INNOVATION LTD
Position:
Signature: /s/ Paul ashley
Date: 16/7/19

SIGNED for and on behalf of
BLUE WATER VACCINES INCORPORATED:

Name: Joseph Hernandez
Position:
Signature: /s/ Joseph Hernandez
Date: 7/3/2019

Exhibit 10.10

Certain portions of this exhibit have been omitted pursuant to Rule 601(b)(10) of Regulation S-K The omitted information is (i) not material and (ii) would likely cause competitive harm to Blue Water Vaccines, Inc. if publicly disclosed. Information that has been omitted has been noted in this document with a placeholder identified by the mark "[***]".

EXCLUSIVE LICENSE AGREEMENT
BETWEEN
ST. JUDE CHILDREN'S RESEARCH HOSPITAL, INC.

&

BLUE WATER VACCINES

ST. JUDE File No.: SJ-11-0001 and SJ-18-0045

LICENSE AGREEMENT

THIS LICENSE AGREEMENT (the "Agreement") is entered into as of January 27, 2020 (the "EFFECTIVE DATE") by and between ST. JUDE CHILDREN'S RESEARCH HOSPITAL, INC., a Tennessee not-for-profit corporation having an address at 262 Danny Thomas Place, Memphis, TN 38105 ("ST. JUDE" or "LICENSOR"), and Blue Water Vaccines, Inc., a Delaware corporation, having an address at 2014 Courtland Avenue, Cincinnati, OH 06830 ("COMPANY") (ST. JUDE and COMPANY hereinafter each referred to as a "PARTY", or collectively referred to as the "PARTIES") with respect to the following:

RECITALS

WHEREAS, as a center for research and education, ST. JUDE is interested in licensing PATENT RIGHTS (hereinafter defined) in a manner that will benefit the public by facilitating the development of useful products; and

WHEREAS, the valuable invention(s) titled "Live, Attenuated *Streptococcus Pneumoniae* Strain and Vaccine for Protection Against Pneumococcal Disease" (ST. JUDE File No.: SJ-11- 0001) and "Vaccine Compositions and Methods for Reducing Transmission of *Streptococcus Pneumoniae*" (ST. JUDE File No.: SJ-18-0045) were developed during the course of research conducted by Dr. Jason Rosch and other members of ST. JUDE (all hereinafter referred to as "INVENTORS" and each individually referred to as an "INVENTOR"); and

WHEREAS, LICENSOR has acquired through assignment by each of the INVENTORS all rights, title and interest, with the exception of certain retained rights by the United States Government, in their interest in said valuable inventions; and

WHEREAS, COMPANY desires to obtain certain rights in such inventions as herein provided, and to provide funding for research related to such inventions at ST. JUDE, if applicable, subject to the terms of a research collaboration agreement(s) to be negotiated by the PARTIES, and to commercially develop, manufacture, use and/or distribute products based upon or embodying said valuable inventions throughout the world; and

NOW THEREFORE, in consideration of the premises and the mutual promises and covenants contained in this Agreement, and for other good and valuable consideration, the receipt and sufficiency of which is hereby acknowledged, the PARTIES hereto agree as follows:

ARTICLE 1
DEFINITIONS

All references to particular Exhibits, Articles or Paragraphs shall mean the Exhibits to, and Paragraphs and Articles of, this Agreement, unless otherwise specified. For the purposes of this Agreement and the Exhibits hereto, the following words and phrases shall have the following meanings:

1.1 AFFILIATED COMPANY" as used herein in either singular or plural shall mean any corporation, company, partnership, joint venture or other entity, which controls, is controlled by or is under common control with COMPANY. For purposes of this Paragraph 1.1, control shall mean the direct or indirect ownership of at least fifty- percent (50%) of the voting or economic interest in said entity. Any AFFILIATED COMPANY that is exercising rights under this AGREEMENT shall provide a written acknowledgement to LICENSOR that they are bound by, and agree to abide by, the terms of this AGREEMENT.

1.2 EFFECTIVE DATE" of this License Agreement shall mean the date set forth above.

1.3 EXCLUSIVE LICENSE" shall mean a grant by LICENSOR to COMPANY of their entire right and interest in the PATENT RIGHTS subject to the exceptions set forth in Article 2.

1.4 FIRST COMMERCIAL SALE" shall mean the first sale for use or consumption by the general public of LICENSED PRODUCT in a country after regulatory approval has been obtained for such LICENSED PRODUCT in such country.

1.5 IND" shall mean an Investigational New Drug application filed with the Food and Drug Administration for authorization to commence human clinical trials in the United States, and its equivalent in other countries or regulatory jurisdictions.

1.6 "LICENSED FIELD" shall mean vaccines for use in humans.

1.7 LICENSED PRODUCT(S)" as used herein in either singular or plural shall mean any material, compositions, drug, or other product, the manufacture, use or sale of which would constitute, but for the license granted to COMPANY pursuant to this Agreement, an infringement of a VALID CLAIM of PATENT RIGHTS (infringement shall include, but is not limited to, direct, contributory, or inducement to infringe).

1.8 NET SALES" shall mean gross sales revenues and fees billed by COMPANY, AFFILIATED COMPANY and SUBLICENSEE(S) from the sale of LICENSED PRODUCT(S) less the following:

(a) customary trade, quantity, or cash discounts to the extent actually allowed and taken;

(b) amounts repaid or credited by reason of rejection or return of LICENSED PRODUCTS;

(c) to the extent separately stated on purchase orders, invoices, or other documents of sale, any taxes or other governmental charges levied on the production, sale, transportation, delivery, or use of a LICENSED PRODUCT, which is paid by or on behalf of COMPANY or AFFILIATES; and

(d) outbound transportation costs prepaid or allowed and costs of insurance in transit.

For purposes of determining NET SALES, the LICENSED PRODUCT(S) shall be deemed to be sold when invoiced and a "sale" shall not include transfers or dispositions for charitable, promotional, pre-clinical, clinical, regulatory or governmental purposes.

1.9 PATENT RIGHTS" shall mean U.S. provisional patent application no. 61/537,290, titled "Live, Attenuated *Streptococcus Pneumoniae* Strain and Vaccine for Protection Against Pneumococcal Disease" filed on September 21, 2011, which issued as US patent number 9,265,819 on February 23, 2016 and U.S. provisional patent application no. 62/817,748 filed March 13, 2019 owned by LICENSOR and all invention(s) disclosed and claimed therein ("INVENTION"), and any issued patents, divisions, continuations, continuations-in-part to the extent that the claims are directed to subject matter described in the above-referenced patent applications and are entitled to the priority date of the existing PATENT RIGHTS, reexaminations, substitutions, renewals, restorations, additions or registrations thereof, as well as non-United States counterparts thereof and extensions and supplementary protection certificates thereon.

1.10 PHASE I CLINICAL TRIAL" shall mean a human clinical trial, the principal purpose of which is a preliminary determination of safety in healthy individuals or patients as required in 21 C.F.R. §312, or a similar clinical study prescribed by the regulatory authorities in a country other than the United States.

1.11 PHASE II CLINICAL TRIAL" shall mean (i) a human clinical trial, for which a primary endpoint is a preliminary determination of efficacy or dose ranges in patients with the disease target being studied as required in 21 C.F.R. §312.21(b), as may be amended from time to time, or a similar clinical study prescribed by the regulatory authorities in a country other than the United States, or (ii) a combined Phase II and Phase III Clinical Trial which enrolls at least forty (40) patients, or any Phase III Clinical Trial performed in lieu of a Phase II study.

1.12 PHASE III CLINICAL TRIAL" shall mean a human clinical trial, the principal purpose of which is to establish safety and efficacy in patients with the disease target being studied as required in 21 C.F.R. §312, or similar clinical study prescribed by the regulatory authorities in a country other than the United States. A Phase III Clinical Trial shall also include any other human clinical trial intended as a pivotal study, whether or not such study is a traditional Phase III study.

1.13 SUBLICENSEE(S)" as used herein in either singular or plural shall mean any person or entity other than an AFFILIATED COMPANY to which COMPANY has granted a sublicense of PATENT RIGHTS under this Agreement.

1.14 VALID CLAIM" as used herein in either singular or plural shall mean a claim of any (i) issued and unexpired patent included within the PATENT RIGHTS unless the claim has been held unenforceable or invalid by the final, un-reversed, and un-appealable decision of a court or other government body of competent jurisdiction, has been irretrievably abandoned or disclaimed, or has otherwise been finally admitted or determined to be invalid, unpatentable or unenforceable, whether through reissue, reexamination, disclaimer or otherwise, or (ii) a pending claim of a patent application within the PATENT RIGHTS to the extent the claim continues to be prosecuted in good faith and has not been cancelled, withdrawn, abandoned or finally disallowed without the possibility of appeal or re-filing of such application.

ARTICLE 2
LICENSE GRANT

2.1 Grant. Subject to the terms and conditions of this Agreement, LICENSOR hereby grants to COMPANY an EXCLUSIVE LICENSE to develop, make, have made, use, import, offer for sale and sell the LICENSED PRODUCT(S) worldwide under the PATENT RIGHTS in the LICENSED FIELD. This license grant shall apply to the COMPANY and any AFFILIATED COMPANY, except that any AFFILIATED COMPANY shall not have the right to sublicense others as set forth in Paragraph 2.2 below. If any AFFILIATED COMPANY exercises rights under this Agreement, such AFFILIATED COMPANY shall be bound by all terms and conditions of this Agreement, including, but not limited to, indemnity and insurance provisions and royalty and other payment provisions, which shall apply to the exercise of the rights, to the same extent as would apply had this Agreement been directly between LICENSOR and the AFFILIATED COMPANY. In addition, COMPANY shall remain fully liable to LICENSOR for all acts and obligations of AFFILIATED COMPANY such that acts of the AFFILIATED COMPANY shall be considered acts of the COMPANY.

2.2 Sublicense. COMPANY may grant sublicenses under the PATENT RIGHTS to third parties under this Agreement, subject to the terms and conditions of this Paragraph 2.2. COMPANY shall provide LICENSOR with a redacted confidential copy of each sublicense agreement between COMPANY and a third party for the grant of rights under the PATENT RIGHTS within forty-five (45) days of its execution. Each sublicense agreement shall: (a) be consistent with the terms, conditions and limitations of this Agreement, (b) name LICENSOR as an intended third party beneficiary of the obligations of SUBLICENSEE without imposition of obligation or liability on the part of LICENSOR or the INVENTORS to the SUBLICENSEE, (c) specifically incorporate Paragraphs 6.2 “Representations by LICENSOR”, 7.1 “Indemnification”, 10.1 “Use of Name”, and 10.4 “Insurance” into the body of the sublicense agreement, and cause the terms used therein to have the same meaning as in this Agreement, and (d) permit the SUBLICENSEE to grant further sublicenses, provided that such sub-sublicensees shall be subject to all of the terms and conditions of this Paragraph 2.2. The redacted copy of each sublicense agreement or sub-sublicense agreement furnished to LICENSOR by COMPANY shall be the Confidential Information of COMPANY. COMPANY shall (a) be and remain responsible for the performance by such SUBLICENSEE, and such SUBLICENSEE’s sublicensees, with the terms of this Agreement, and any action by a SUBLICENSEE, and such SUBLICENSEE’s sublicensees, that would, if conducted by COMPANY, be a breach of this Agreement, shall be deemed a breach of this Agreement by COMPANY, and (b) ascertain, calculate, audit and collect all royalties that become payable by such SUBLICENSEE, and such SUBLICENSEE’s sublicensees, hereunder and take appropriate enforcement action against such SUBLICENSEE, and such SUBLICENSEE’s sublicensees, for any failure to pay or to properly calculate payments.

For the avoidance of doubt, an agreement between any of COMPANY, an AFFILIATED COMPANY or a SUBLICENSEE and a third party granting rights (in the absence of consideration to COMPANY, AFFILIATED COMPANY, or SUBLICENSEE) to the third party to perform research or development activities solely on behalf of COMPANY, AFFILIATED COMPANY, or SUBLICENSEE, but not rights to commercialize or otherwise exploit LICENSED PRODUCTS, shall not be deemed to be a sublicense hereunder and shall not be subject to the terms of this Paragraph 2.2; provided, however, that COMPANY will remain solely responsible for such agreements and the actions of any party it contracts with thereunder.

2.3 Government Rights. The United States Government may have acquired a nonexclusive, nontransferable, irrevocable, paid-up license to practice or have practiced for or on behalf of the United States the INVENTIONS described in PATENT RIGHTS throughout the world. The rights granted herein are additionally subject to: (i) the requirement that any LICENSED PRODUCT(S) produced for use or sale within the United States shall be substantially manufactured in the United States (unless a waiver under 35 USC § 204 or equivalent is granted by the appropriate United States government agency), (ii) the right of the United States government to require LICENSORS, or their licensees, including COMPANY, to grant sublicenses under the PATENT RIGHTS to responsible applicants on reasonable terms when necessary to fulfill health or safety needs, and, (iii) other rights acquired by the United States government under the laws and regulations applicable to the grant/contract award under which the inventions were made.

2.4 LICENSOR Retained Rights. LICENSOR retains the right to make, have made, provide and use for LICENSOR’S non-commercial research and clinical purposes, including the ability to distribute LICENSOR’S biological materials disclosed and/or claimed in PATENT RIGHTS for nonprofit academic research use to non-commercial entities as is customary in the scientific community and to sell the biological materials as research reagents for research use only by the scientific community.

ARTICLE 3
FEES, ROYALTIES, & PAYMENTS

3.1 License Fee. COMPANY shall pay to LICENSOR within thirty (30) days of the EFFECTIVE DATE a license fee as set forth in Exhibit A. LICENSOR will not submit an invoice for the license fee, which is nonrefundable and shall not be credited against royalties or other fees.

3.2 Annual Maintenance Fee. COMPANY shall pay to LICENSOR the annual maintenance fee as set forth in Exhibit A. These annual maintenance fees shall be due, without invoice from LICENSOR, within thirty (30) days each anniversary of the EFFECTIVE DATE beginning with the first anniversary. Running royalties and Milestone Payments accrued under, respectively, Paragraph 3.3 and Paragraph 3.5 and paid to LICENSOR during the preceding calendar year shall be credited against the minimum annual royalties due the following year. For example, running royalties and milestone payments accrued under and paid to LICENSOR during calendar year 2020 shall be credited against the annual maintenance fee due and payable no later than January 30, 2021.

3.3 Running Royalties. COMPANY shall pay to LICENSOR a running royalty as set forth in Exhibit A, for each LICENSED PRODUCT(S) sold by COMPANY, AFFILIATED COMPANIES and/or SUBLICENSEE(S), based on NET SALES for the term of this Agreement. Such payments shall be made quarterly. All non-US taxes related to LICENSED PRODUCT(S) sold under this Agreement shall be paid by COMPANY and shall not be deducted from royalty or other payments due to LICENSOR.

In order to insure LICENSOR the full royalty payments contemplated hereunder, COMPANY agrees that in the event any LICENSED PRODUCT(S) shall be sold to a corporation, firm or association (the "PURCHASER") with which COMPANY shall have any agreement, understanding or arrangement with respect to consideration (such as, among other things, an option to purchase stock or actual stock ownership, or an arrangement involving division of profits or special rebates or allowances) received by COMPANY with respect to sale of such LICENSED PRODUCT(S), the royalties to be paid hereunder to LICENSOR for such LICENSED PRODUCT(S) shall be based upon the greater of: 1) the net selling price (per NET SALES) at which the PURCHASER resells such LICENSED PRODUCT(S) to the end user, 2) the fair market value of the LICENSED PRODUCT(S) as of the date that COMPANY receives such consideration from such PURCHASER, or 3) the net selling price (per NET SALES) of LICENSED PRODUCT(S) paid by the PURCHASER.

3.4 Sublicense Consideration. In addition to the running royalty as set forth under Paragraph 3.3, COMPANY shall pay to LICENSOR, as set forth on Exhibit A a percentage of consideration received for sublicenses (collectively, "SUBLICENSE CONSIDERATION" as further defined below in this Paragraph 3.4) under this Agreement, solely to the extent that such consideration relates to the value of a sublicense to the PATENT RIGHTS but (i) subject to the limitations set forth below and (ii) excluding consideration that relates to the value of other intellectual property rights licensed by COMPANY to such SUBLICENSEE. This SUBLICENSE CONSIDERATION shall be due, without the need for invoice from LICENSOR, within forty-five (45) days of the receipt of any SUBLICENSE CONSIDERATION payment made to COMPANY by a SUBLICENSEE under a sublicense agreement. Such SUBLICENSE CONSIDERATION shall mean consideration of any kind received by the COMPANY from a SUBLICENSEE(S) for the grant of a sublicense under this Agreement, such as upfront fees or milestone fees and including any premium paid by the SUBLICENSEE(S) over Fair Market Value (as such term is defined in Paragraph 3.3(c) below) for stock of the COMPANY in consideration for such sublicense. However, not included in such SUBLICENSE CONSIDERATION are:

(a) Support for research, development (product development, clinical studies and regulatory), and/or manufacturing activities corresponding directly to the development of LICENSED PRODUCT(S), which do not exceed the fully- burdened cost for undertaking such research, development, and/or manufacturing performed by or for the COMPANY or AFFILATED COMPANY (including third parties on their behalf), each pursuant to a specific agreement including a performance plan and commensurate budget;

(b) Proceeds derived from debt financing, to the extent that such financing is at market rates, and any loans to COMPANY or AFFILIATED COMPANY by SUBLICENSEE:

(c) Consideration received for the purchase of an equity interest in COMPANY to the extent that the price per share for such equity does not exceed by more than twenty-five percent (25%) the Fair Market Value of COMPANY's stock. The term Fair Market Value shall mean the average price that the stock in question is publicly trading at for twenty (20) days prior to the announcement of its purchase by the SUBLICENSEE(S) or if the stock is not publicly traded, the value of such stock as determined by the most recent private financing through a financial investor (an entity whose sole interest in the COMPANY or AFFILIATED COMPANY is financial) of the COMPANY or AFFILIATED COMPANY that issued the shares;

(d) As reimbursement of COMPANY's patent costs related to PATENT RIGHTS;

(e) Amounts paid to the COMPANY or AFFILIATED COMPANY by the SUBLICENSEE(S) for royalties on Licensed Products which are subject to payments to LICENSOR under Paragraph 3.3.

3.5 Milestone Payments. COMPANY shall pay to LICENSOR the milestone payments as set forth in Exhibit B for the term of this Agreement. All non-US taxes (excluding any taxes based on LICENSOR'S income) related to milestone payments shall be paid by COMPANY and shall not be deducted from payments due to LICENSOR.

3.6 Patent Reimbursement. COMPANY will reimburse LICENSOR, within thirty (30) days of the EFFECTIVE DATE the amount of $ [***] for costs associated with the preparation, filing, maintenance, and prosecution of PATENT RIGHTS in the LICENSED FIELD incurred by LICENSOR on or before January 27, 2020. In accordance with Paragraph 4.1 below, COMPANY will reimburse LICENSOR, within thirty (30) days of the receipt of an invoice from LICENSOR, for all reasonable costs associated with the preparation, filing, maintenance, and prosecution of PATENT RIGHTS in the LICENSED FIELD incurred by LICENSOR subsequent to January 28, 2020. Each invoice submitted to COMPANY by LICENSOR shall include copies of the actual invoices from LICENSOR'S patent counsel.

3.7 Form of Payment. All payments under this Agreement shall be made in U.S. Dollars. Checks are to be made payable to "St. Jude Children's Research Hospital". Wire transfers may be made using the following information:

Acct Name: St. Jude Children's Research Hospital, Master Concentration Account
Acct Number: 00-0270040
Bank Name: First Tennessee
Bank Bank Swift: FTNMUS44
Bank ABA #: 084-000026
Bank Address: Post Office Box 84
Memphis, TN 38101
USA

COMPANY shall be responsible for any and all costs associated with wire transfers and shall include a reference to this Agreement in any wire transfer payment. Payments made by check should be sent to the following address:

St. Jude Children's Research Hospital
P.O. Box 1000, Department # 516
Memphis, TN 38148-0516

3.8 Late Payments. In the event that any payment due hereunder is not made when due, the payment shall accrue interest beginning on the tenth day following the due date thereof, calculated at the annual rate of the sum of (a) two percent (2%) plus (b) the prime interest rate quoted by The Wall Street Journal on the date said payment is due, the interest being compounded on the last day of each calendar quarter, provided however, that in no event shall said annual interest rate exceed the maximum legal interest rate for corporations. Each such payment when made shall be accompanied by all interest so accrued. Said interest and the payment and acceptance thereof shall not negate or waive the right of LICENSOR to seek any other remedy, legal or equitable, to which it may be entitled because of the delinquency of any payment including, but not limited to termination of this Agreement as set forth in Paragraph 9.2.

ARTICLE 4
PATENT PROSECUTION, MAINTENANCE, & INFRINGEMENT

4.1 Prosecution & Maintenance. COMPANY will bear all expenses relating to the filing, prosecution, and maintenance of all PATENT RIGHTS after the EFFECTIVE DATE. Upon approval of the law firm by LICENSOR, COMPANY may oversee future patent prosecution using its patent counsel and pay patent expenses directly, so long as LICENSOR is copied on all correspondence and notified prior to any substantive actions. Title to all patents and patent applications shall reside in LICENSOR. COMPANY shall (a) cause its patent counsel to timely copy LICNESOR on all official actions and written correspondence with any patent office, and (b) allow LICENSOR and/or its counsel an opportunity and reasonably sufficient time to comment and advise COMPANY with respect thereto. COMPANY shall consider in good faith and reasonably incorporate all comments and advice from LICENSOR. At least thirty (30) days in advance of any filing or response deadline, or fee due date, COMPANY may elect not to have a patent application filed in any particular country or not to pay expenses associated with prosecuting or maintaining any patent application or patent within PATENT RIGHTS, provided that COMPANY pays for all costs incurred up to LICENSOR'S receipt of such notification. Failure to provide such notification will be considered by LICENSOR to be COMPANY's willingness to proceed at COMPANY's expense. Upon such notification, at LICENSOR'S own expense, LICENSOR may file, prosecute, and/or maintain such patent applications or patent within the PATENT RIGHTS with respect to which COMPANY has made the foregoing decision(s) (collectively, the "COMPANY-ABANDONED PATENTS"), and any rights or license granted hereunder held by COMPANY, AFFILIATED COMPANIES or SUBLICENSEE(S) relating to COMPANY-ABANDONED PATENTS shall terminate.

4.2 Notification. Each PARTY will notify the other promptly in writing when any infringement by a third party is uncovered or suspected.

4.3 Infringement. COMPANY shall have the first right to enforce any patent within PATENT RIGHTS against any infringement or alleged infringement thereof, and shall at all times keep LICENSOR informed as to the status thereof. Before COMPANY commences an action with respect to any infringement of such patents, COMPANY shall give careful consideration to the views of LICENSOR and to potential effects on the public interest in making its decision whether or not to sue. Thereafter, COMPANY may, at its own expense, institute suit against any such infringer or alleged infringer and control and defend such suit in a manner consistent with the terms and provisions hereof and recover any damages, awards or settlements resulting therefrom, subject to Paragraph 4.5. However, no settlement, consent judgment or other voluntary final disposition of the suit may be entered into without the prior written consent of LICENSOR, which consent shall not be unreasonably withheld. This right to sue for infringement shall not be used in an arbitrary or capricious manner. LICENSOR shall reasonably cooperate in any such litigation at COMPANY's expense.

If COMPANY elects not to enforce any patent within the PATENT RIGHTS, then it shall so notify LICENSOR in writing within ninety (90) days of receiving notice that an infringement exists. LICENSOR may, in its sole judgment and at its own expense, take steps to enforce any patent and control, settle, and defend such suit in a manner consistent with the terms and provisions hereof, and recover, for its own account, any damages, awards or settlements resulting therefrom. Before LICENSOR commences an action with respect to any infringement of such patents, LICENSOR shall give careful consideration to the views of COMPANY and to potential effects on COMPANY'S interests under this Agreement in making its decision whether or not to sue and thereafter shall at all times keep COMPANY informed as to the status thereof, as long as COMPANY is licensed under said patents.

4.4 Patent Invalidity Suit. If a declaratory judgment action is brought naming COMPANY as a defendant and alleging invalidity of any of the PATENT RIGHTS, LICENSOR may elect to take over the sole defense of the action at its own expense. COMPANY shall cooperate fully with LICENSOR in connection with any such action. LICENSOR shall give careful consideration to the views of COMPANY and to potential effects on COMPANY'S interests under this Agreement in any such defense and thereafter shall at all times keep COMPANY informed as to the status thereof, as long as COMPANY is licensed under said patents.

4.5 Recovery. In any action taken pursuant to Section 4.3, COMPANY and LICENSOR shall recover their respective actual out-of-pocket expenses (including attorneys' fees), or equitable proportions thereof, associated with the action or settlement thereof from any resulting recovery made by either PARTY with the PARTY controlling the action having first entitlement to recover its out-of-pocket expenses if the recovery is insufficient to reimburse both PARTIES for their out-of-pocket expenses. Any excess amount of such a recovery shall be shared and distributed as follows: the PARTY initiating such action, shall retain seventy-five percent (75%) of such excess amount and twenty-five percent (25%) paid to the non-initiating PARTY.

4.6 Concerns regarding PATENT RIGHTS In the event COMPANY has concerns regarding the validity, patentability or enforceability of the PATENT RIGHTS, COMPANY shall provide LICNESOR written notice of such concern. Within fourteen (14) days after receipt of such notice, a senior executive officer of LICENSOR, and a senior executive officer of COMPANY shall meet in person or by teleconference and exchange written summaries reflecting the nature and extent of the concern, and at this meeting they shall use their reasonable endeavors to resolve the dispute. If, within a further period of thirty (30) days, or if in any event within ninety (90) days following initial receipt of the notice from COMPANY, the concern has not been resolved, then the parties may pursue other dispute resolution mechanisms.

ARTICLE 5
OBLIGATIONS OF THE PARTIES

5.1 Reports. COMPANY shall provide to LICENSOR the following written reports, which reports shall be Confidential Information of COMPANY, according to the following schedules.

(a) COMPANY shall provide calendar quarterly royalty reports, substantially in the format of Exhibit C and due within thirty (30) days of the end of each calendar quarter following the FIRST COMMERCIAL SALE of a LICENSED PRODUCT. Royalty Reports shall disclose the amount of LICENSED PRODUCT(S) sold, the total NET SALES of such LICENSED PRODUCT(S), and the running royalties due to LICENSOR as a result of NET SALES by COMPANY, AFFILIATED COMPANIES and SUBLICENSEE(S) thereof. Payment of any such royalties due shall accompany such Royalty Reports.

(b) Until such time as COMPANY, an AFFILIATED COMPANY or a SUBLICENSEE(S) has achieved a FIRST COMMERCIAL SALE of a LICENSED PRODUCT, or received FDA market approval, COMPANY shall provide annual diligence reports, due within thirty (30) days of the end of every December following the EFFECTIVE DATE of this Agreement. These diligence reports shall describe COMPANY's, AFFILIATED COMPANY's or any SUBLICENSEE(S)'s technical efforts towards meeting its obligations under the terms of this Agreement, particularly its progress toward achieving the developmental milestones set forth in Exhibit B and shall explain any delays experienced in achieving such milestones relative to the projected dates for achievement set forth in Exhibit B.

(c) COMPANY shall further provide in conjunction with the annual report due in January pursuant to 5.1(b) or the quarterly royalty report due in the last calendar quarter of each calendar year pursuant to Paragraph 5.1(a), the following information:

(i) evidence of insurance as required under Paragraph 10.4, or, a statement of why such insurance is not currently required; and

(ii) identification of all AFFILIATED COMPANIES which have exercised rights pursuant to Paragraph 2.1, or, a statement that no AFFILIATED COMPANY has exercised such rights;

(iii) identification of (A) all SUBLICENSEE(S) with which COMPANY has entered into an agreement pursuant to the terms of Paragraph 2.2 and all (B) sublicensee(s) of such SUBLICENSEE(S) with which such SUBLICENSEE(S) have entered into agreements pursuant to the terms of Paragraph 2.2, in each case since the previous annual report; and

(iv) notice of all FDA approvals of any LICENSED PRODUCT(S) obtained by COMPANY, AFFILIATED COMPANY or SUBLICENSEE, the patent(s) or patent application(s) licensed under this Agreement upon which such product or service is based, and the commercial name of such product or service, or, in the alternative, a statement that no FDA approvals have been obtained.

5.2 Records. COMPANY shall make and retain, for a period of three (3) years following the period of each report required by Paragraph 5.1(a), true and accurate records, files and books of account containing all the data reasonably required for the full computation and verification of sales and other information required in Paragraph 5.1(a). Such books and records shall be in accordance with generally accepted accounting principles consistently applied. COMPANY shall permit the inspection of such records, files and books of account by LICENSOR'S agent (the "Auditor"), which Auditor shall be a nationally recognized auditor acceptable to COMPANY, such acceptance not to be unreasonably withheld, and subject to obligations of confidentiality and nonuse reasonably acceptable to COMPANY. Any such inspection shall occur during regular business hours upon ten (10) business days' written notice to COMPANY. Such inspection shall not be made more than once each calendar year. All costs of such inspection shall be paid by LICENSOR, provided that if any such inspection shall reveal that an error has been made resulting in an underpayment equal to five percent (5%) or more of any payment due to LICENSOR, the costs of such inspection shall be borne by COMPANY. As a condition to entering into any such agreement, COMPANY shall include in any agreement with its AFFILIATED COMPANIES or its SUBLICENSEE(S) which permits such party to make, use, sell or import the LICENSED PRODUCT(S), a provision requiring such party to retain records of sales of LICENSED PRODUCT(S) and other information as required in Paragraphs 5.1(a) and this Paragraph 5.2 and permit the Auditor to inspect such records as required by this Paragraph 5.2. All information and records made available to the Auditor pursuant to this Paragraph 5.2 shall be deemed to be and treated as Confidential Information of COMPANY pursuant to Article 8.

5.3 Commercially Reasonable Efforts. COMPANY shall exercise commercially reasonable efforts to develop and to introduce the LICENSED PRODUCT(S) into the commercial market as soon as practicable, consistent with sound and reasonable business practice and judgment; thereafter, until the expiration or termination of this Agreement, COMPANY shall endeavor to keep LICENSED PRODUCT(S) reasonably available to the public. COMPANY shall also exercise commercially reasonable efforts to develop LICENSED PRODUCT(S) suitable for different indications within the LICENSED FIELD, so that the PATENT RIGHTS can be commercialized as broadly and as speedily as good scientific and business judgment would deem possible. Developmental milestones for a LICENSED PRODUCT are outlined in Exhibit B. Should COMPANY fail to achieve the developmental milestones and COMPANY and LICENSOR fail to agree upon a mutually satisfactory revised time line, LICENSOR shall be allowed to terminate this Agreement pursuant to Paragraph 9.2.

5.4 Other Products. After clinical evidence has been provided in writing by LICENSOR to COMPANY demonstrating the practicality of a particular market or use of PATENT RIGHTS within the LICENSED FIELD which is not being developed or commercialized by COMPANY, COMPANY shall either provide LICENSOR with a reasonable development plan and start commercially reasonable efforts to develop in that particular market or use or make commercially reasonable efforts to sublicense the particular market or use to a third party. If within six (6) months of such notification by LICENSOR, COMPANY has not initiated such development efforts or initiated efforts to sublicense that particular market or use, LICENSOR may terminate this license for such particular market or use. This Paragraph 5.4 shall not be applicable if COMPANY reasonably demonstrates to LICENSOR that commercializing such LICENSED PRODUCT(S) or granting such a sublicense in said market or use would have a substantial adverse effect upon the ability of COMPANY to market or sell the LICENSED PRODUCT(S) being developed or being sold by COMPANY.

5.5 Patent Acknowledgement. COMPANY agrees that all packaging containing individual LICENSED PRODUCT(S) sold by COMPANY, AFFILIATED COMPANIES and SUBLICENSEE(S) of COMPANY will be marked with the number of the applicable patent(s) licensed hereunder in accordance with each country's patent laws.

ARTICLE 6
REPRESENTATIONS

6.1 Duties of the Parties. LICENSOR is an institute of research and education and not a commercial organization. Therefore, LICENSOR has no ability to evaluate the commercial potential of any PATENT RIGHTS or LICENSED PRODUCT or other license or rights granted in this Agreement. It is therefore incumbent upon COMPANY to evaluate the rights and products in question, to examine the materials and information provided by LICENSOR and to determine for itself the validity of any PATENT RIGHTS, its freedom to operate, and the value of any LICENSED PRODUCTS or other rights granted.

6.2 Representations by LICENSOR. LICENSOR warrants that it has good and marketable title to its interest in the PATENT RIGHTS with the exception of certain retained rights of the United States Government, which may apply if any part of the research was funded in whole or in part by the United States Government. LICENSOR does not warrant the validity of any patents or that practice under such patents shall be free of infringement. EXCEPT AS EXPRESSLY SET FORTH IN THIS PARAGRAPH 6.2, COMPANY, AFFILIATED COMPANIES AND SUBLICENSEE(S) AGREE THAT THE PATENT RIGHTS, ARE PROVIDED "AS IS", AND THAT LICENSOR MAKES NO REPRESENTATION OR WARRANTY WITH RESPECT TO THE PERFORMANCE OF LICENSED PRODUCT(S) INCLUDING THEIR SAFETY, EFFECTIVENESS, OR COMMERCIAL VIABILITY. LICENSOR DISCLAIMS ALL WARRANTIES WITH REGARD TO PRODUCT(S) LICENSED UNDER THIS AGREEMENT, INCLUDING, BUT NOT LIMITED TO, ALL WARRANTIES, EXPRESSED OR IMPLIED, OF MERCHANTABILITY AND FITNESS FOR ANY PARTICULAR PURPOSE. NOTWITHSTANDING ANY OTHER PROVISION OF THIS AGREEMENT, LICENSOR ADDITIONALLY DISCLAIMS ALL OBLIGATIONS AND LIABILITIES ON THE PART OF LICENSOR AND INVENTORS, FOR DAMAGES, INCLUDING, BUT NOT LIMITED TO, DIRECT, INDIRECT, SPECIAL, AND CONSEQUENTIAL DAMAGES, ATTORNEYS' AND EXPERTS' FEES, AND COURT COSTS (EVEN IF LICENSORS HAVE BEEN ADVISED OF THE POSSIBILITY OF SUCH DAMAGES, FEES OR COSTS), ARISING OUT OF OR IN CONNECTION WITH THE MANUFACTURE, USE, OR SALE OF THE PRODUCT(S) LICENSED UNDER THIS AGREEMENT. COMPANY, AFFILIATED COMPANIES AND SUBLICENSEE(S) ASSUME ALL RESPONSIBILITY AND LIABILITY FOR LOSS OR DAMAGE CAUSED BY A PRODUCT MANUFACTURED, USED, OR SOLD BY COMPANY, ITS SUBLICENSEE(S) AND AFFILIATED COMPANIES WHICH IS A LICENSED PRODUCT(S) AS DEFINED IN THIS AGREEMENT.

ARTICLE 7
INDEMNIFICATION

7.1 Indemnification. COMPANY, AFFILIATED COMPANY and SUBLICENSEE(S) shall indemnify, defend with counsel reasonably acceptable to LICENSOR, and hold LICENSOR, the American Lebanese Syrian Associated Charities, Inc. (ALSAC; a non- profit, 501(c)(3) corporation which supports ST. JUDE), their present and former trustees, directors, governors, officers, INVENTORS of PATENT RIGHTS, agents, faculty, employees and students harmless as against any claims, demands, damages, judgments, fees (including reasonable attorneys fees), expenses, or other costs arising from or incidental to a breach of any representation, warranty or covenant made by COMPANY in this Agreement, any product liability or other lawsuit, claim, demand or other action brought by a third party as a consequence of the practice of the PATENT RIGHTS by COMPANY, AFFILIATED COMPANY and SUBLICENSEE(S), whether or not LICENSORS or said INVENTORS, either jointly or severally, are named as a party defendant in any such lawsuit and whether or not LICENSOR or the INVENTORS are alleged to be negligent or otherwise responsible for any injuries to persons or property. Practice of the PATENT RIGHTS covering the LICENSED PRODUCT(S) by an AFFILIATED COMPANY or an agent or a SUBLICENSEE(S) or a third party on behalf of or for the account of COMPANY or by a third party who purchases LICENSED PRODUCT(S) from COMPANY, shall be considered COMPANY's practice of said PATENT RIGHTS for purposes of this Paragraph. The obligation of COMPANY to defend, indemnify and hold harmless as set out in this Paragraph shall survive the termination of this Agreement, shall continue even after assignment of rights and responsibilities to an AFFILIATE COMPANY or SUBLICENSEE, and shall not be limited by any other limitation of liability elsewhere in this Agreement.

ARTICLE 8
CONFIDENTIALITY

8.1 Confidentiality. If necessary, the Parties will exchange information they consider to be confidential. The recipient of such information agrees to accept the disclosure of said information, including but not limited to the terms of this Agreement and any reports or information provided by COMPANY pursuant to Article 5 ("Confidential Information"). The recipient of Confidential Information agrees to employ all reasonable efforts to maintain the Confidential Information secret and confidential, such efforts to be no less than the degree of care employed by the recipient to preserve and safeguard its own confidential information. The Confidential Information shall not be disclosed or revealed to anyone except employees of the recipient which employees (i) have a need to know the Confidential Information, (ii) are subject to obligations of confidentiality and non-use substantially similar to those set forth in this Article 8, and (iii) have been advised by the recipient of the confidential nature of the Confidential Information and that the Confidential Information shall be treated accordingly.

COMPANY may disclose Confidential Information to the extent that such disclosure is:

(A) **Required by Governmental Order**. Made in response to a valid order of a court of competent jurisdiction or other supra-national, federal, national, regional, state, provincial or local governmental or regulatory body of competent jurisdiction; provided, however, that COMPANY shall first have given notice to LICENSOR and given LICENSOR a reasonable opportunity to quash such order and to obtain a protective order requiring that the Confidential Information and documents that are the subject of such order be held in confidence by such court or agency or, if disclosed, be used only for the purposes for which the order was issued; and provided further that if a disclosure order is not quashed or a protective order is not obtained, the Confidential Information disclosed in response to such court or governmental order shall be limited to that information which is legally required to be disclosed in response to such court or governmental order;

(B) **Required by Law.** Otherwise required by law; provided, however, that COMPANY shall (a) provide LICENSOR with reasonable advance notice of and an opportunity to comment on any such required disclosure, (b) if requested by LICENSOR, seek confidential treatment with respect to any such disclosure to the extent available, and (c) use good faith efforts to incorporate the comments of LICENSOR in any such disclosure or request for confidential treatment;

(C) **Required by Regulatory Authority.** Made by COMPANY to the regulatory authorities as required in connection with any filing, application or request for regulatory approval; provided, however, that reasonable measures shall be taken to assure confidential treatment of such information;

(D) **Required by Agreement.** Made by COMPANY, in connection with the performance of this Agreement, to AFFILIATED COMPANIES, SUBLICENSEES, research parties, employees, consultants, representatives or agents, each of whom prior to disclosure must be bound by obligations of confidentiality and non-use at least equivalent in scope to those set forth in this Paragraph 8.1; or

(E) **Required by Certain Third Parties**. Made by COMPANY to existing or potential acquirers or merger candidates; existing or potential SUBLICENSEES; investment bankers; existing or potential investors, venture capital firms or other financial institutions or investors for purposes of obtaining financing; or AFFILIATED COMPANIES, each of whom prior to disclosure must be bound by obligations of confidentiality and non-use at least equivalent in scope to those set forth in this Paragraph 8.1.

The obligations of this Paragraph shall also apply to AFFILIATED COMPANIES and/or SUBLICENSEE(S) that are provided such Confidential Information by COMPANY. LICENSOR'S, COMPANY's, AFFILIATED COMPANIES', and SUBLICENSEES' obligations under this Paragraph shall extend until three (3) years after the termination of this Agreement.

8.2 Exceptions. The recipient's obligations under Paragraph 8.1 shall not extend to any part of the Confidential Information:

a. that can be demonstrated to have been in the public domain or publicly known and readily available to the trade or the public prior to the date of the disclosure; or

b. that can be demonstrated, from written records to have been in the recipient PARTY's possession or readily available to the recipient PARTY from another source not under obligation of secrecy to the disclosing PARTY prior to the disclosure; or

c. that becomes part of the public domain or publicly known by publication or otherwise, not due to any unauthorized act by the recipient PARTY; or

d. that is demonstrated from written records to have been developed by or for the receiving PARTY without reference to Confidential Information disclosed by the disclosing PARTY.

e. that is required to be disclosed by law, government regulation or court order.

8.3 Right to Publish. LICENSOR may publish manuscripts, abstracts or the like describing the PATENT RIGHTS and inventions contained therein provided Confidential Information of COMPANY, as defined in Paragraph 8.1, is not included or without first obtaining written approval from COMPANY to include such Confidential Information. Otherwise, LICENSOR and the INVENTORS shall be free to publish manuscripts and abstracts or the like without prior approval. The text of the proposed manuscripts, abstracts or the like containing any COMPANY Confidential Information must be provided to COMPANY at least sixty (60) days prior to the date of submission for consideration for manuscripts, abstracts or the like in order to provide COMPANY an opportunity to comment on such proposed manuscripts, abstracts or the like and determine if COMPANY Confidential Information is disclosed therein. In the event that COMPANY so comments prior to such intended submission date, LICENSOR shall (x) delay submission of such manuscripts, abstracts or the like thirty (30) days beyond such intended submission date and, during such thirty (30) day period, engage in good faith discussion of such comments with COMPANY, and (y) consider in good faith the modification of such proposed manuscripts, abstracts or the like pursuant to such comments. Upon the request of COMPANY, LICENSOR shall remove COMPANY Confidential Information from any proposed manuscripts, abstracts or the like.

ARTICLE 9
TERM & TERMINATION

9.1 Term. The term of this Agreement shall commence on the EFFECTIVE DATE and shall continue, in each country, until the date of expiration of the last to expire VALID CLAIM included within PATENT RIGHTS in that country.

9.2 Termination by Either PARTY. This Agreement may be terminated by either COMPANY or LICENSOR, in the event that the other PARTY (a) files or has filed against it a petition under the Bankruptcy Act, makes an assignment for the benefit of creditors, has a receiver appointed for it or a substantial part of its assets, or otherwise takes advantage of any statute or law designed for relief of debtors or (b) fails to perform or otherwise breaches any of its obligations hereunder, if, following the giving of notice by the terminating PARTY of its intent to terminate and stating the grounds therefor, the PARTY receiving such notice shall not have cured such failure or breach within sixty (60) days. In no event, however, shall such notice or intention to terminate be deemed to waive any rights to damages or any other remedy which the PARTY giving notice of breach may have as a consequence of such failure or breach.

9.3 Termination by COMPANY. COMPANY may terminate this Agreement and the license granted herein, for any reason, upon giving LICENSOR thirty (30) days written notice.

9.4 Obligations and Duties upon Termination. If this Agreement is terminated, the PARTIES shall be released from all obligations and duties imposed or assumed hereunder to the extent so terminated, except as expressly provided to the contrary in this Agreement. Upon termination, each PARTY shall cease any further use of the Confidential Information received from the other PARTY. Termination of this Agreement, for whatever reason, shall not affect the obligation of any PARTY to make any payments for which it is liable prior to or upon such termination. Termination shall not affect LICENSOR'S right to recover unpaid royalties, fees, reimbursement for patent expenses, or other forms of financial compensation incurred prior to termination. Upon termination, COMPANY shall submit a final royalty report to LICENSOR and any royalty payments (if after first commercial sale of LICENSED PRODUCTS), fees, unreimbursed patent expenses and other financial compensation due to LICENSOR shall become immediately payable. Furthermore, upon termination of this Agreement, all rights in and to the PATENT RIGHTS shall revert immediately to LICENSOR at no cost to LICENSOR. Upon termination of this Agreement, any SUBLICENSEE(S) shall become with such SUBLICENSEE(S)' agreement a direct licensee of LICENSOR, provided that LICENSOR'S obligations to SUBLICENSEE(S) are no greater than LICENSOR'S obligations to COMPANY under this Agreement. COMPANY shall provide written notice of such to each SUBLICENSEE(S) with a copy of such notice provided to LICENSOR.

ARTICLE 10
MISCELLANEOUS

10.1 Use of Name or Logo. COMPANY, AFFILIATED COMPANIES and SUBLICENSEE(S) shall not use the name or logo of LICENSOR or American Lebanese Syrian Associated Charities, or any of their constituent parts, such as St. Jude Children's Research Hospital or ALSAC any contraction thereof or the name of INVENTORS in any advertising, promotional, sales literature or fundraising documents without prior written consent from an authorized representative of ST. JUDE, as applicable. LICENSOR will not use publicly for publicity, promotion, or otherwise, any logo, name, trade name, service mark, or trademark of COMPANY, its AFFILIATED COMPANIES, and SUBLICENSEE(S) or any simulation, abbreviation, or adaptation of the same, or the name of any COMPANY employee or agent, without COMPANY's prior, written, express consent. COMPANY, AFFILIATED COMPANIES and SUBLICENSEE(S) shall allow at least seven (7) business days notice of any proposed public disclosure for LICENSOR'S review and comment or to provide written consent. LICENSOR shall allow at least seven (7) business days notice of any proposed public disclosure for COMPANY, AFFILIATED COMPANIES or SUBLICENSEE(S) review and comment or to provide written consent.

10.2 No Partnership. Nothing in this Agreement shall be construed to create any agency, employment, partnership, joint venture or similar relationship between LICENSOR and COMPANY other than that of a licensor/licensee. Neither LICENSOR nor COMPANY shall have any right or authority whatsoever to incur any liability or obligation (express or implied) or otherwise act in any manner in the name or on the behalf of the other, or to make any promise, warranty or representation binding on the other.

10.3 Notice of Claim. Each, LICENSOR and COMPANY, shall give the other or its representative immediate notice of any suit or action filed, or prompt notice of any claim made, against them arising out of the performance of this Agreement or arising out of the practice of the INVENTIONS licensed hereunder.

10.4 Insurance. Prior to initial human testing or FIRST COMMERCIAL SALE of any LICENSED PRODUCT(S) as the case may be and thereafter so long as LICENSED PRODUCTS are being sold in any particular country COMPANY and SUBLICENSEES shall establish and maintain appropriate insurance coverage in the minimum amount of five million dollars ($5,000,000) per claim, with an aggregate of ten million dollars ($10,000,000), to cover any liability arising from COMPANY'S indemnification obligations under Article 7 above with respect to such human testing or commercial sale of LICENSED PRODUCT. Prior to initial human testing or FIRST COMMERCIAL SALE of any LICENSED PRODUCT(S) as the case may be and thereafter so long as LICENSED PRODUCTS are being sold in any particular country, COMPANY and SUBLICENSEES shall establish and maintain, in each country in which COMPANY, an AFFILIATED COMPANY or SUBLICENSEE(S) shall test or sell LICENSED PRODUCT(S), product liability or other appropriate insurance coverage in the minimum amount of five million dollars ($5,000,000) per claim. COMPANY will annually present evidence, in the form of a statement in the annual report to LICENSOR that such coverage is being maintained. Upon LICENSOR'S request, COMPANY will furnish LICENSOR with a Certificate of Insurance of each insurance policy obtained. LICENSOR and ALSAC shall be listed as additional insureds in COMPANY's said insurance policies. If such insurance is underwritten on a 'claims made' basis, COMPANY agrees that any change in underwriters during the term of this Agreement and thereafter so long as LICENSED PRODUCTS are being sold will require the purchase of 'prior acts' coverage to ensure that coverage will be continuous throughout the term of this Agreement and thereafter so long as LICENSED PRODUCTS are being sold.

10.5 Governing Law and Venue. In the event that legal action is brought arising from this Agreement, it shall be brought in Memphis, Tennessee and shall be governed by the laws of the State of Tennessee, without regard to conflicts of law provisions thereof.

10.6 Notice. All notices or communication required or permitted to be given by either PARTY hereunder shall be deemed sufficiently given if mailed by registered mail or certified mail, return receipt requested, or sent by overnight courier, such as Federal Express, to the other PARTY at its respective address set forth below or to such other address as one PARTY shall give notice of to the others from time to time hereunder or if sent by email to the other PARTY as provided below. Mailed notices shall be deemed to be received on the third business day following the date of mailing. Notices sent by overnight courier shall be deemed received the following business day.

If to COMPANY:

Blue Water Vaccines
2014 Courtland Avenue
Cincinnati, OH 06830
Attn.: Joseph Hernandez
Phone:
Email:jhernandez@bluewatervaccines.com

With a copy to:
Erin Henderson
6308 SW 35th Way
Gainesville, FL 32608
404-405-6315
ehenderson@bluewatervaccines.com

If to ST. JUDE:

Office of Technology Licensing
Attn. Associate Director
St. Jude Children's Research Hospital
262 Danny Thomas Place
Memphis, Tennessee
Phone: (901) 595-2751
Shawn.hawkins@stjude.org

10.7 Compliance with All Laws. In all activities undertaken pursuant to this Agreement, LICENSOR and COMPANY covenant and agree that each will in all material respects comply with such Federal, state and local laws and statutes, as may be in effect at the time of performance and all valid rules, regulations and orders thereof regulating such activities.

10.8 Successors and Assigns. Neither this Agreement nor any of the rights or obligations created herein, except for the right to receive any remuneration hereunder, may be assigned by either PARTY, in whole or in part, without the prior written consent of the other PARTIES, except that either PARTY shall be free to assign this Agreement in connection with any sale of substantially all of its assets without the consent of the other, but shall provide written notice of such assignment within thirty (30) days of its occurrence. This Agreement shall bind and inure to the benefit of the successors and permitted assigns of the PARTIES hereto.

10.9 No Waivers; Severability. No waiver of any breach of this Agreement shall constitute a waiver of any other breach of the same or other provision of this Agreement, and no waiver shall be effective unless made in writing. Any provision hereof prohibited by or unenforceable under any applicable law of any jurisdiction shall as to such jurisdiction be deemed ineffective and deleted herefrom without affecting any other provision of this Agreement. It is the desire of the PARTIES hereto that this Agreement be enforced to the maximum extent permitted by law, and should any provision contained herein be held by any governmental agency or court of competent jurisdiction to be void, illegal and unenforceable, the PARTIES shall negotiate in good faith for a substitute term or provision which carries out the original intent of the PARTIES.

10.10 Entire Agreement; Amendment. COMPANY and LICENSOR acknowledge that they have read this entire Agreement and that this Agreement, including the attached Exhibits constitutes the entire understanding and contract between the PARTIES hereto and supersedes any and all prior or contemporaneous oral or written communications with respect to the subject matter hereof. It is expressly understood and agreed that (i) there being no expectations to the contrary between the PARTIES hereto, no usage of trade, verbal agreement or another regular practice or method dealing within any industry or between the PARTIES hereto shall be used to modify, interpret, supplement or alter in any manner the express terms of this Agreement; and (ii) this Agreement shall not be modified, amended or in any way altered except by an instrument in writing signed by both of the PARTIES hereto.

10.11 Delays or Omissions. Except as expressly provided herein, no delay or omission to exercise any right, power or remedy accruing to any PARTY hereto, shall impair any such right, power or remedy to such PARTY nor shall it be construed to be a waiver of any such breach or default, or an acquiescence therein, or in any similar breach or default be deemed a waiver of any other breach or default theretofore or thereafter occurring. Any waiver, permit, consent or approval of any kind or character on the part of any PARTY of any breach or default under this Agreement, or any waiver on the part of any PARTY of any provisions or conditions of this Agreement, must be in writing and shall be effective only to the extent specifically set forth in such writing. All remedies either under this Agreement or by law or otherwise afforded to any PARTY, shall be cumulative and not alternative.

10.12 Force Majeure. If a PARTY fails to fulfill its obligations hereunder (other than an obligation for the payment of money), when such failure is due to an act of God, or other circumstances beyond its reasonable control, including but not limited to fire, flood, civil commotion, riot, war (declared and undeclared), revolution, epidemics, terrorism, earthquake or embargoes, then said failure shall be excused for the duration of such event and for such a time thereafter as is reasonable to enable the parties to resume performance under this Agreement, provided however, that in no event shall such time extend for a period of more than one hundred eighty (180) days.

10.13 Further Assurances. Each PARTY shall, at any time, and from time to time, prior to or after the EFFECTIVE DATE of this Agreement, at reasonable request of the other PARTY, execute and deliver to the other such instruments and documents and shall take such actions as may be required to more effectively carry out the terms of this Agreement.

10.14 Survival. All representations, warranties, covenants and agreements made herein and which by their express terms or by implication are to be performed after the execution and/or termination hereof, or are prospective in nature, shall survive such execution and/or termination, as the case may be. This shall include Paragraphs 3.8 (Late Payments), 5.2 (Records), and Articles 6, 7, 8, 9, and 10.

10.15 No Third Party Beneficiaries. Nothing in this Agreement shall be construed as giving any person, firm, corporation or other entity, other than the PARTIES hereto and their successors and permitted assigns, any right, remedy or claim under or in respect of this Agreement or any provision hereof.

10.16 Headings. Article headings are for convenient reference and not a part of this Agreement. All Exhibits are incorporated herein by this reference.

10.17 Counterparts. This Agreement may be executed in counterparts, each of which shall be deemed an original and all of which when taken together shall be deemed but one instrument.

IN WITNESS WHEREOF, this Agreement shall take effect as of the EFFECTIVE DATE when it has been executed below by the duly authorized representatives of the parties.

BLUE WATER VACCINE, INC.	**ST. JUDE CHILDREN'S RESEARCH HOSPITAL, INC.**
/s/ Joseph Hernandez	/s/ J. Scott Elmer
Name: Joseph Hernandez	Name: J. Scott Elmer
Title: Chief Executive Officer	Title: Director, Office of Technology Licensing
January 27, 2020	
(Date)	(Date)

EXHIBIT A. LICENSE FEE & ROYALITIES.
EXHIBIT B. DEVELOPMENTAL MILESTONES & MILESTONE PAYMENTS
EXHIBIT C. SALES & ROYALTY REPORT FORM.

EXHIBIT A

LICENSE FEE & ROYALTIES

1. License Fee: The initial license fee due under Paragraph 3.1 within thirty (30) days of the EFFECTIVE DATE is fifteen thousand US dollars [***].

2. Annual Maintenance Fee: The annual maintenance fee pursuant to Paragraph 3.2 is ten thousand US dollars ($10,000) per year, beginning on the first anniversary of the effective date of the license, provided the annual maintenance fee shall be waived if all developmental milestones scheduled for completion before the annual fee is due according to Exhibit B have been achieved.

3. Royalties: The running royalty rate payable under Paragraph 3.3 is four percent (4%).

In the event COMPANY is required to enter into one or more third party license agreements to practice Patent Rights, the royalty payments due LICENSOR may be reduced by a percentage equal to half of that paid to such third party. However, in no event shall the milestone payments due to LICENSOR be reduced by more than one half of the original royalty percentage.

SUBLICENSE CONSIDERATION: COMPANY shall pay LICENSOR Fifteen percent (15%) of any SUBLICENSE CONSIDERATION.

EXHIBIT B

DEVELOPMENTAL MILESTONES & MILESTONE PAYMENTS

1. Developmental Milestones: Developmental Milestones by COMPANY for a LICENSED PRODUCT in accord with Paragraph 5.3 are as follows:

Complete IND enabling study	2020
Initiate animal toxicology study	last half 2020
File IND	first half 2021
Complete PHASE I CLINICAL TRIAL	first half of 2022
Commence PHASE II CLINICAL TRIAL	2024
Commence PHASE III CLINICAL TRIAL	2026
Regulatory approval, US or foreign equivalent	2026

2. Milestone Payments: The Milestone Payments payable under Paragraph 3.5 are as follows:

Upon Commencement of PHASE III CLINICAL TRIAL	[***]
Upon regulatory approval, US or foreign equivalent	[***]
Upon FIRST COMMERCIAL SALE	[***]

“Commence” or “Commencement” of either a PHASE I, PHASE II or PHASE III CLINCIAL TRIAL shall mean the dosing of the first patient in such PHASE I, PHASE II, or PHASE III CLINICAL TRIAL.

EXHIBIT C

SALES & ROYALTY REPORT

FOR LICENSE AGREEMENT BETWEEN BLUE WATER VACCINES AND ST. JUDE CHILDREN'S RESEARCH HOSPITAL DATED

FOR PERIOD OF _____ TO _____

TOTAL ROYALTIES DUE FOR THIS PERIOD $ _____

PRODUCT ID	PRODUCT OR SERVICE NAME	*ST. JUDE REFERENCE	1st COMMERCIAL SALE DATE	TOTAL GROSS SALES	TOTAL REDUCTIONS	TOTAL NET SALES	ROYALTY RATE	AMOUNT DUE
		SJ-11-0001 SJ-18-0045						

* Please provide the ST. JUDE Reference Number or Patent Reference

This report format is to be used to report quarterly royalty statements to ST. JUDE. It should be placed on COMPANY letterhead and accompany any royalty payments due for the reporting period. This report shall be submitted even if no sales are reported.

Exhibit 23.1

CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

We consent to the inclusion in this Amendment No. 1 to this Registration Statement on Form S-1 and related prospectus of our report dated August 20, 2021, with respect to the financial statements of Blue Water Vaccines, Inc. (Company) as of December 31, 2020 and 2019, and for the two years then ended (which report includes an explanatory paragraph regarding the existence of substantial doubt about the Company's ability to continue as a going concern), and to the reference to us under the heading "Experts" in this Registration Statement and accompanying prospectus on Form S-1.

/s/ Mayer Hoffman McCann P.C.

Los Angeles, California
November 4, 2021