## VIA EDGAR

November 4, 2021

U.S. Securities & Exchange Commission Division of Corporation Finance Office of Energy & Transportation 100 F Street, NE Washington, D.C. 20549

Attn: Ms. Lauren Hamill and Ms. Celeste Murphy

Re: Blue Water Vaccines Inc.

**Registration Statement on Form S-1** 

Filed October 8, 2021 File No. 333-260137

Dear Ms. Hamill and Ms. Murphy:

Blue Water Vaccines Inc. (the "Company," "we," "our" or "us") hereby transmits the Company's response to the comment letter received from the staff (the "Staff") of the U.S. Securities and Exchange Commission (the "Commission") on October 21, 2021, regarding Registration Statement on Form S-1.

For the Staff's convenience, we have repeated below the Staff's comments in bold, and have followed each comment with the Company's response.

# Form S-1 filed on October 8, 2021 Pipeline, page 2

1. We note your response to prior comment 4. With respect to your pipeline table on pages 2, 63 and 77, we previously noted that the "status" column for the Norovirus/Malaria row of the pipeline table indicates that you plan to start IND-enabling studies for this candidate in the second half of 2022, and that such statement appears speculative and premature, particularly in light of your disclosure that your current cash position is sufficient to fund your operations only until Q2 2022 and that your ability to continue as a going concern beyond that point is contingent upon obtaining funding from this offering. In your response, you point out that your revisions on page 4 of prospectus summary state your expectation that your existing cash along with the proceeds of the offering will be sufficient for at least 12 months following the closing of this offering. You further state: "As such, [the] pipeline projections included in the S-1 assume the obtaining of funding from the offering." Particularly since your pipeline table first appears on page 2 of the S-1 and precedes the revised disclosure on page 4 that you reference in your response, please further revise your pipeline table to indicate, by footnote including a cross-reference or otherwise, that your disclosures in the "status" column of the table assume you will obtain critical funding from this offering that, in combination with your current cash position, you expect will allow you to continue to operate for at least 12 months following the closing.

In response to the Staff's comment, we have revised the pipeline figure on pages 2, 66 and 80 of the amended S-1 to indicate that all pipeline projections are contingent upon obtaining funding from the contemplated offering.

## We have broad discretion in the use of the net proceeds from this offering..., page 51

2. We note your response to prior comment 9 and your revised risk factor disclosure on page 51, which appears to attempt to reserve the right of management to change the use of proceeds from this offering. The disclosure now states: "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, use the proceeds in ways that differ from the anticipated uses set forth in this prospectus."

We redirect your attention to Instruction 7 to Item 504 of Regulation S-K, which allows your company to reserve the right to change the use of proceeds, provided such reservation is due to certain contingencies that are discussed specifically and the alternatives to such use in the event of such contingencies are indicated. Here, your revisions to your risk factor disclosure do not address the specific "outcomes of [your] preclinical studies and other research" that could cause management to use and spend any proceeds from the offering differently than stated in Use of Proceeds. Further, the revised disclosure does not indicate management's intended alternative uses for the offering proceeds in the event certain outcomes of preclinical studies and other research occur.

Therefore, please revise both your risk factor and Use of Proceeds disclosures accordingly. In so doing, please ensure that the disclosures in both sections of your registration statement are consistent with each other. We note that as drafted your Use of Proceeds section appears to describe management's broad discretion with respect to the "amounts and timing" of expenditures from the proceeds, whereas your risk factor disclosure appears to more broadly describe management's discretion with respect to the "use and spending" of any proceeds.

In response to the Staff's comment, we have revised the Risk Factor disclosure on page 52 and Use of Proceeds disclosure on page 58 to further illuminate potential outcomes warranting reallocation of proceeds and clarifying that 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. Further to your comment, we have edited the referenced sections to provide consistent disclosure.

## Capitalization, page 60

3. We note your response to prior comment 9 and that you will have 2,172,371 shares of common stock outstanding as of September 30, 2021 (after giving effect to the conversion of all outstanding shares of preferred stock into an aggregate of 1,372,371 shares). Please explain to us how you calculated the conversion of the 1,146,138 outstanding preferred stock into 1,372,271 shares considering the issuance price and conversion are the same.

In response to the Staff's comment, we note that the referenced disclosure has been updated to reflect outstanding shares as of October 31, 2021. The number of shares of common stock into which the preferred stock will be converted was determined by multiplying the existing number of shares of preferred stock (1,146,138) by the conversion ratio, which is obtained by adding the accrued dividends as of October 31, 2021, to the initial issue price of \$6.09.

4. We note on page F-15 that 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. Please explain to us how you will meet the conversion requirements for the Series Seed preferred stock to convert upon your IPO.

In response to the Staff's comment, we have revised the disclosure on pages 10, 53, 63 and 144 of the amended S-1. As mentioned in our previous communication, pursuant to a consent dated October 7, 2021, holders of all of the outstanding shares of preferred stock have consented to an optional conversion pursuant to Section 4 of our amended and restated certificate of incorporation which was adopted on July 1, 2019. The numbers included in the amended S-1 also account for the Pre-IPO Stock Split which is summarized in the Summary section of the S-1 on page 8 of the amended S-1.

#### **Our Vaccine Platform**

### Structure, page 80

5. We note your response to prior comment 13. While you have removed one reference to "potent" and replaced it with the word "strong" at the top of page 81, we note that a new reference to "potent platforms" has been added on page 80. Further, we note that the reference to "potent" remains in a sub-section heading on page 82 ("S60 nanoparticles may serve as a polyvalent potent vaccine platform"). While you have insert a citation to a published study in this sub-section heading, it is unclear whether the results of such cited study related to the potency of the vaccine platform that S60 nanoparticles "may" provide. In relation to these references to "potent" platforms, we reissue the prior comment.

In response to the Staff's comment, we have revised the disclosure on pages 86 of the amended S-1. We have removed the word potent from the disclosure.

- 6. We refer to the second bullet on page 80 which states: "There are several preclinical animal studies have showed P24/S60 chimeric vaccine candidates have high protective effects against viral pathogens or diseases. As set forth below in Table 1."
  - Please revise Table 1 and any other tables or graphics throughout your filing to ensure that the text in each, including subscript or other notations are clearly legible.
  - Please revise your disclosure and/or your table to clarify what Table 1 on page 81 is intended to reflect. We note that the items shown in the table should be easily identifiable from and tie to the description of those items in the disclosure above. While your bulleted disclosure on page 80 references references "several preclinical animal studies," it is not clear which studies are being referred to and how they may relate to information in Table 1. Further, the bulleted disclosure preceding the table indicates that such animal studies "showed that P24/S60 chimeric vaccine candidates have high protective effects against viral pathogens or diseases," but the level or degree of protective effect does not appear to shown in Table 1.
  - Please also revise to clarify what the numbers in the column labeled "Reference" in Table 1 on page 81 mean. Additionally, we note that another table captioned "Table 1" has been added in this section on page 82.
  - To aid investor understanding and for the avoidance of confusion, please renumber the second table on page 82.
  - The same comment given with respect to the Table 1 included on page 81 applies.

We note that you appear to have included footnote citations "(a)" through "(e)" in the column labeled "epitope/antigen," and there appears to be a footnote citation "(f)" in the heading for the column labeled "significant immune enhancement in mice." However, in each case there is no corresponding footnote disclosure under the table. Please revise as appropriate. Additionally, please indicate, by footnote or otherwise, what the acronyms or abbreviations in the "epitope/antigen" column mean as you didin the table included on page 81.

• It is unclear what "ND" in the column labeled "significant immune enhancement in mice" means. Please revise to provide explanatory disclosure in order for an investor to understand the table.

In response to the Staff's comment, we have revised the disclosure on pages 83, 84, 85, 86, 88, 89, 90, 91, 95, 96, 98, and 99 of the amended S-1 to ensure tables and graphics included in the S-1 are legible.

In response to the Staff's comment, we have revised the disclosure page 83 and 84 of the amended S-1 to clarify what Table 1 is intended to reflect. Further, we have revised the disclosure to tie to the disclosure above Table 1.

In response to the Staff's comment, we have revised the disclosure on pages 83, 84, 85, 86, 88, 89, 90, 91, 95, 96, 98, 99, and 102 of the amended S-1 to renumber the tables and figures throughout the disclosure for greater understanding and avoidance of confusion.

In response to the Staff's comment, we have revised the disclosure on page 83 and 85 of the amended S-1 to clarify what Table 2 is intended to reflect. Further, we have revised the disclosure to tie to the disclosure above Table 2.

In response to the Staff's comment, we have revised the disclosure on page 86 of the amended S-1 to provide the footnote citations for Table 2.

In response to the Staff's comment, we have revised the disclosure on page 86 of the amended S-1 to provide clarification of the "ND" column label in the footnote to Table 2.

## BWV-201 Streptococcus pneumoniae (S. pneumoniae) Vaccine, page 88

7. We note your response to second part of prior comment 17. Please revise your disclosure and/or Figure A on page 90 to help investors better understand the preclinical head-to head results your response notes you have included to compare your vaccine strain to Prevnar 7, Prevnar 13 and Pneumovax. For example, the names of the vaccines and strains shown on the x-axis in the graph should be easily identifiable from and tie to the description of those items in the narrative disclosure above the graph. Explain what "Percent" on the y-axis measures.

In response to the Staff's comment, we have revised the disclosure on page 95 of the amended S-1. We have added language to Figure 7 (Formerly Figure A) further clarifying the information presented.

## BWV-302: Norovirus-malaria vaccine program, page 95

- 8. We acknowledge the addition of disclosure beginning on page 95 regarding your BWV- 302 vaccine program for Norovirus-Malaria in response to prior comment 5. We have the following additional comments:
  - In the first paragraph in this section captioned "Our Vaccine," please revise to provide additional context for the following statement: "The researchers, Xi Jason Jiang, Ph.D., and Ming Tan, Ph.D., demonstrated that S60 VLPs could be used to present foreign antigens on the surface of the S60 VLP. Further, it has also demonstrated that foreign antigens could also be expressed on the surface of the P24 VLP." Please explain how the co-researchers for your norovirus-malaria combination vaccine "demonstrated" these findings by briefly describing the researchers' relevant work or studies.
  - The last sentence in "Our Vaccine" states as follows with respect to your mouse immunization study: "These data demonstrate the potential of our vaccine candidate against malaria." Based on your disclosure in the "status" column of your pipeline table for BWV-302, which indicates that you intend to begin IND-enabling studies for BWV-302 in the second half of 2022, it appears that you do not expect to be able to rely on this mouse immunization study data to support an IND application. Please revise your disclosure to briefly explain what additional pre-IND enabling studies or steps you expect to have to conduct or take prior to proceeding with IND

The paragraph in this section captioned "Development" states as follows: "Following IND submission, if accepted, we intend to initiate our Phase I clinical trial in healthy adults ages 18 to 54 in the first half of 2023." We note that you disclose your intended timing of Phase 1 clinical trials for BWV-302 without having first addressed when you plan to submit your IND application. Given the early stage of development for this candidate, and your statement in your pipeline table that you do not plan to initiate IND-enabling studies for this candidate until the second half of 2022, this statement regarding clinical trial commencement is premature and speculative and should be removed.

In response to the Staff's comment, we have revised the disclosure on page 100 to refer to previous disclosure of the  $S_{60}$  and  $P_{24}$  particle description provided on pages 82-84, 87, 92, 96-102 of the amended S-1.

In response to the Staff's comment, we have revised the disclosure on page 102 of the amended S-1. We have disclosed an additional study we wish to undertake. The current mouse study will be use as part of IND application package, however, we feel it important to further investigate efficacy by conducting an animal challenge study.

#### **Intellectual Property, page 114**

- 9. We note your response to prior comment 18. We have the following additional comments:
  - With respect to your pending patent applications, please revise the disclosure in your various tabular presentations to disclose the type of patent protection sought for each product or technology (composition of matter, use, or process).
  - We note your disclosure that the CHMC license agreement may end upon the last-to expire patent on a jurisdiction by jurisdiction and product by product basis. Please revise your tabular presentation of the issued and pending patents under this agreement to clarify when the last of these patents are expected to expire in both the U.S. and any foreign jurisdictions.

In response to the Staff's comment, we have revised the disclosure on pages 68, 69, 119, 122 and 124 of the amended S-1. We have disclosed the type of patent protection being sought for each of the pending patent applications in the tabular presentations.

In response to the Staff's comment, we respectfully note that we have previously disclosed on page 119 the anticipated last to expire patent date for each of the issued and pending patents, based on current information.

10. We note your revisions in response to prior comment 19, which we reissue. Revise your disclosures regarding each of your license and option agreements to include a discussion of all material payment terms, including quantification of the following:

- *Up-front or execution payments paid or received.* In this regard, we refer you by way of example and not limitation to phrases such as "a one-time five-digit initial license fee" on page 115.
- Annual maintenance fees.
- Aggregate amounts paid or received.
- Aggregate future potential milestone payments to be paid or received.
- Profit or revenue-sharing provisions.

• Applicable royalty rates to be paid by each party. In the event a range is provided in place of the actual royalty rate, such range should be within ten percentage points. In this regard, we refer you to your reference on page 117 to "double-digit royalties to be paid on any sums received by the Company from any sublicensee under the terms of the OUI Agreement" and on page 119 to the Company's obligation to pay "a double-digit percentage of other consideration received for any sublicenses" under the St. Jude License Agreement. Also, with respect to the OUI license agreement, please revise your disclosure on page 118 to state the highest "minimum sum" of royalties that must be paid to OUI in any year before application of the "step down." Please disclose the period of years over which the step-down will apply before the minimum sum is reduced to zero.

Additionally, please revise your IP disclosure to define acronyms at first use. For instance, we note that in a description of a development milestone on page 115, you use the acronym "first commercial sale in ROW" without defining "ROW," which appears again later in this section.

In response to the Staff's comment, we have revised the disclosure on pages 120, 121, 122, and 124 of the amended S-1. We have disclosed more detailed information about the up-front or execution payments and aggregate amounts paid thus far to each entity, aggregate milestones payments broken down into three categories: development, regulatory and commercial, provided information related to profit sharing or revenue sharing provisions and refined the double-digit royalty payments to be within ten percentage points. Further, we have clarified the meaning of "ROW" on Page 123.

11. We note your revisions in response prior comment 20, and that you have now disclosed the "minimum" amount of funding the Company provided to Oxford University in January 2020 for three years of salary for Dr. Craig Thompson as a condition of entering into the OUI license agreement. To the extent known, please revise your disclosure to provide the maximum amount that the Company may be required to pay to fund three years of salary for Dr. Craig Thompson, and when such additional payment(s) will be due. Disclose any factors that will impact the amount of annual salary for the relevant three-year period so as to determine the ultimate amount the Company will be obligated to pay, or advise.

In response to the Staff's comment, we have revised the disclosure on page 122 of the amended S-1. We have disclosed that 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

We thank the Staff for its review of the foregoing. If you have further comments, please feel free to contact our counsel, Jessica Yuan, at jyuan@egsllp.com or by telephone at (212) 370-1300.

Sincerely,

/s/ Joseph Hernandez

Joseph Hernandez Chief Executive Officer

cc: Jessica Yuan, Esq.