United States securities and exchange commission logo

October 21, 2021

Joseph Hernandez
Chief Executive Officer
Blue Water Vaccines Inc.
201 E. Fifth Street, Suite 1900
Cincinnati, OH 45202

Re: Blue Water Vaccines Inc.
Registration Statement on Form S-1
Filed October 8, 2021
File No. 333-260137

Dear Mr. Hernandez:

We have reviewed your registration statement and have the following comments. In some of our comments, we may ask you to provide us with information so we may better understand your disclosure.

Please respond to this letter by amending your registration statement and providing the requested information. If you do not believe our comments apply to your facts and circumstances or do not believe an amendment is appropriate, please tell us why in your response.

After reviewing any amendment to your registration statement and the information you provide in response to these comments, we may have additional comments.

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.

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.

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.
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.
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.
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.

Please revise to clearly tie the information presented in the table to your disclosure.

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 did in 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.

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.

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 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-

enabling studies.
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.

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.

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.

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.

We remind you that the company and its management are responsible for the accuracy and adequacy of their disclosures, notwithstanding any review, comments, action or absence of action by the staff.

Refer to Rules 460 and 461 regarding requests for acceleration. Please allow adequate time for us to review any amendment prior to the requested effective date of the registration statement.

You may contact Tara Harkins at 202-551-3639 or Mary Mast at 202-551-3613 if you have questions regarding comments on the financial statements and related matters. Please contact Lauren Hamill at 303-844-1008 or Celeste Murphy at 202-551-3257 with any other questions.

Sincerely,

FirstName LastNameJoseph Hernandez

Division of Corporation Finance

Comapany NameBlue Water Vaccines Inc.

Office of Life Sciences

cc: Jessica Yuan

FirstName LastName