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

FORM 8-K

CURRENT REPORT

Pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934

Date of Report (Date of earliest event reported): July 20, 2022

Blue Water Vaccines Inc.

(Exact name of registrant as specified in its charter)

Delaware	001-41294	83-2262816
(State or other Jurisdiction	(Commission File Number)	(IRS Employer
of Incorporation)		Identification No.)
201 E. Fifth Street, Suite 1900 Cincinnat	i, Ohio	45202
(Address of Principal Executive Office	es)	(Zip Code)
Registrant's	telephone number, including area code: (5	13) 620-4101
(Former 1	name or former address, if changed since la	ast report.)
Check the appropriate box below if the Form 8-K fill following provisions:	ing is intended to simultaneously satisfy	the filing obligation of the registrant under any of the
☐ Written communications pursuant to Rule 425 unde	r the Securities Act (17 CFR 230.425)	
\square Soliciting material pursuant to Rule 14a-12 under the	ne Exchange Act (17 CFR 240.14a-12)	
☐ Pre-commencement communications pursuant to Ru	ule 14d-2(b) under the Exchange Act (17 C	FR 240.14d-2(b))
☐ Pre-commencement communications pursuant to Ru	ule 13e-4(c) under the Exchange Act (17 C	FR 240.13e-4(c))
Securities registered pursuant to Section 12(b) of the Ac	t:	
Title of Each Class	Trading Symbol(s)	Name of Each Exchange on Which Registered
Common Stock, par value \$0.00001 per share	BWV	The Nasdaq Stock Market LLC
Emerging growth company ⊠		
If an emerging growth company, indicate by check mark or revised financial accounting standards provided pursu		e extended transition period for complying with any new \Box

Item 1.01 Entry into Material Definitive Agreement.

On July 20, 2022, Blue Water Vaccines Inc. (the "Company") entered into a Sponsored Research Agreement (the "SRA"), effective as of June 30, 2022 (the "Effective Date"), by and between the Company and Children's Hospital Medical Center, d/b/a Cincinnati Children's Hospital Medical Center ("CHMC") relating to the exploration and research of vaccine development of the Company's norovirus shell and protrusion (S&P) platform for multiple diseases. The term of the SRA is one year from the Effective Date, and is renewable by mutual agreement of the parties. The research project will be supervised and directed as principal investigator by Ming Tan, Ph.D. If for any reason, Mr. Tan is unavailable to serve as principal investigator and the parties are unable to find a replacement within sixty days of such unavailability, the SRA may be terminated by either party.

Pursuant to the SRA, CHMC is required to fulfill certain research requirements and periodically report the research projects' progress and results to the Company. Additionally, the SRA provides that the Company will provide for payments of costs and expenses relating to the research and also provide additional funding in connection with the research in a sum of up to \$247,705.

The foregoing description is qualified in its entirety by reference to the SRA, which is filed herewith as Exhibit 10.1 hereto and is incorporated by reference herein.

Item 7.01 Regulation FD Disclosure.

On July 20, 2022, the Company issued a press release announcing the entry into the SRA. A copy of the press release is furnished as Exhibit 99.1 hereto.

The foregoing information (including Exhibit 99.1) is being furnished pursuant to Item 7.01 and will not be deemed to be filed for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), or otherwise be subject to the liabilities of that section, nor will it be deemed to be incorporated by reference in any filing under the Securities Act of 1933, as amended, or the Exchange Act.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits

10.1	Sponsored Research Agreement, effective as of June 30, 2022, by and between Blue Water Vaccines Inc. and Children's Hospital Medical
	Center, d/b/a Cincinatti Children's Hospital Medical Center.
99.1	Press Release, dated July 20, 2022
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)

SIGNATURE

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

Date: July 25, 2022

Blue Water Vaccines Inc.

By: /s/ Joseph Hernandez

Joseph Hernandez Chief Executive Officer

SPONSORED RESEARCH AGREEMENT

THIS SPONSORED RESEARCH AGREEMENT is made and effective as of June 30, 2022 (the "Effective Date") by and between Children's Hospital Medical Center, d/b/a Cincinnati Children's Hospital Medical Center ("CHMC") located at 3333 Burnet Avenue, Cincinnati, Ohio 45229-3039, and Blue Water Vaccines, located at 201 E. Fifth Street, Suite 1900, Cincinnati, Ohio 45202, ("Sponsor").

WHEREAS, CHMC has developed proprietary knowledge related to norovirus P and S domain particles as carriers for viral antigen display and VLP vaccine development;

WHEREAS, the parties desire that CHMC conduct a research program funded by Sponsor titled "Production and Evaluation of the P24 and S60 Nanoparticles Displaying Antigens" described in Exhibit A (the "Research Program"); and

WHEREAS, the Research Program contemplated by this Agreement is of mutual interest and benefit to CHMC and Sponsor and will further the instructional, research and treatment objectives of CHMC in a manner consistent with its status as a non-profit, tax-exempt, educational and patient care institution.

NOW, THEREFORE, the parties hereto agree as follows:

- **1. STATEMENT OF WORK.** CHMC agrees to perform the Research Program in accordance with the research plan set forth in the statement of work (the "<u>Statement of Work</u>") attached hereto as <u>Exhibit</u> A. CHMC and PI (as defined below) will have the freedom to conduct and supervise the Research Program in a manner consistent with CHMC's research and patient care mission.
- **2. PRINCIPAL INVESTIGATOR.** The Research Program will be supervised and directed by Ming Tan, Ph.D. (the "PI"). If, for any reason, s(he) is unable to continue to serve as PI and a successor acceptable to both CHMC and Sponsor is not available within sixty (60) days of the beginning of such unavailability, this Agreement may be terminated by either party upon written notice without liability to either party.
- **3. REPORTS.** PI will provide Sponsor with written summaries of Research Program progress every six (6) months. A final report will be provided to Sponsor within ninety (90) days after the expiration or termination of this Agreement. Sponsor will have the non-exclusive right to use the information in such summaries and final report for any reasonable purpose, provided that such use does not infringe any of CHMC's patents that are not expressly licensed to Sponsor pursuant to Paragraph 8(g). However, Sponsor may not charge fees for such information or use it for advertising or promotional activities without CHMC's prior written consent. Moreover, to the extent that the reports contain any of CHMC's Confidential Information, then Sponsor's use will also be subject to the confidentiality obligations set forth in Section 6, as well as the publication provisions set forth in Section 7A.
- **4. REIMBURSEMENT OF COSTS AND PAYMENT.** Sponsor will reimburse CHMC for all direct and indirect costs incurred in the performance of the Research Program, which will not exceed the total estimated cost of Two hundred forty-seven thousand seven hundred five dollars (\$247,705) without written authorization from Sponsor. Sponsor acknowledges that this amount is a good faith estimate only and not a guarantee of the cost to conduct the Research Program. If CHMC determines that it will require additional funds, it will provide Sponsor written notice and an estimate of the additional amounts needed. Payments will be made to CHMC by Sponsor in U.S. Dollars (without setoff for any currency conversions) drawn on a US bank, made payable by wire or electronic transfer to "Children's Hospital Medical Center" and sent to CHMC as follows:

Bank Name: PNC Bancorp

Bank Address: 201 East Fifth Street, Cincinnati, OH 45202

ABA# 041000124 Swift Code: PNCCUS33

Account Name: Children's Hospital Medical Center

Account Number: 4006905132 Ref: ID/ Dr.Tan SRA0000297 Such payments will identify the Research Program (SRA0000297) and PI (Dr. Ming Tan) and will be paid as follows: 60% of the total budget within 30 days of receipt of an invoice upon execution; 20% at the midpoint of the term of the SRA within 30 days of receipt of an invoice; and 20% within 30 days of receipt of an invoice after CHMC has provided the final report to the Sponsor. A final financial accounting of all costs incurred and all funds received by CHMC hereunder together with a check for the amount of the unexpended balance, if any, will be submitted to Sponsor within ninety (90) days following the completion of the Research Program or termination of this Agreement. Both parties acknowledge and agree that the terms of this Agreement are commercially reasonable and the payments provided are consistent with fair market value for general commercial purposes without regard, directly or indirectly, to the volume or value of any referrals or other business generated or which could in the future be generated between the parties.

5. TERM; TERMINATION.

- A. <u>Term; Termination for Convenience</u>. The term of this Agreement ("<u>Term</u>") will begin on the Effective Date and will continue for one (1) year thereafter and may renew or be extended only by mutual agreement of the parties. This Agreement may be terminated upon sixty (60) days written notice by either party for convenience
- B. <u>Termination For Breach</u>. This Agreement may also be terminated by either party upon written notice for the other party's breach of its material obligations hereunder, provided that it will have first given written notice of such breach to the breaching party in reasonable detail, and the breaching party will have failed to cure such breach within thirty (30) days after receipt of such notice.
- C. <u>Termination for Insolvency or Bankruptcy</u>. Either party may terminate this Agreement by written notice if the other party (i) becomes insolvent or otherwise unable to pay its debts as they become due (unless it cures such condition within thirty (30) days after receipt of written notice of a claim of insolvency from the other party); (ii) makes a general assignment for the benefit of its creditors; or (iii) becomes 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.
- D. <u>Effect of Termination</u>. Upon expiration or termination for any reason, CHMC will be reimbursed in accordance with Section 4 for all costs and non-cancelable commitments incurred in connection with the performance of the Research Program prior to expiration or termination. The following provisions will survive expiration or termination of this Agreement: Articles 3-4, 6, 7, and 9-26, and Sections 5.D., 8.A., 8.E. and 8.G. (to the extent that any Option Period extends through the expiration date of this Agreement).

6. USE OF NAMES; PUBLICITY; CONFIDENTIAL INFORMATION.

A. <u>Names; Publicity</u>. Neither party will make any commercial use of the names, logos, trademarks or service marks of the other party or its affiliates or any of their officers, employees, students, investigators or board members, or make any press release or similar public announcement or disclosure of this Agreement (other than merely the fact that it exists) without the prior written permission of the other party. The disclosing party will provide copies of the proposed disclosure reasonably in advance (but in no event less than fifteen (15) business days) before such proposed 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.

- B. 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 Research Program, Program Inventions, Patents, Biological Materials, or the transmitting party's research or business, 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 results, samples, data, drawings, trade secrets, draft or non-filed final versions of filings or other correspondence with the United States Patent and Trademark Office and other patent registration offices, and the terms of this Agreement. However, Confidential Information does not include materials or information that the receiving party can substantiate by 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, agents or affiliates; or (e) was independently developed by the receiving party without use of the disclosing party's Confidential Information.
- C. <u>Confidentiality Obligations</u>. 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 in connection with this Agreement 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 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. Notwithstanding the foregoing, each party may keep one (1) copy of the other party's Confidential Information to the extent needed to confirm compliance with the terms of this Agreement. Each party will be responsible for any breach of confidentiality hereunder by any of its affiliates, sublicensees, employees, consultants or other independent contractors. Each party will advise the other immediately in the event that it learns or has reason to believe that any person under its reasonable control has disclosed or used or intends to disclose or use such other party's Confidential Information and the remedial or preventative actions being taken.
- D. <u>Required Disclosures</u>. Notwithstanding the foregoing, CHMC and Sponsor 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 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 federal, state and local government(s) and non-profit research funding agencies and their agents as necessary in connection with any funding related to the Research Program, Program Inventions, Technology or Patents.
- E. <u>Injunctive Relief</u>. The parties each acknowledge and agree that a breach of this Section 6 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 may be entitled to seek injunctive relief in addition to any other remedy provided in this Agreement or available at law.
- F. <u>Duration</u>. The party's respective confidentiality obligations will remain in effect for five (5) year(s) after the expiration or termination of this Agreement.

7. PUBLICATIONS: OUTSIDE ACTIVITIES.

A. <u>Publications</u>. CHMC reserves the right for itself and its affiliates and investigators to present, publish or otherwise disseminate the results of the Research Program and information regarding the Program Inventions. However, during the Term, CHMC agrees to submit to Sponsor copies of any abstract or manuscript proposed for written or oral presentation or publication at least thirty (30) days in advance of the submission or presentation or seven (7) days in the case of an abstract. If Sponsor does not, within thirty (30) days after receipt of the manuscript or seven (7) days in the case of an abstract, object in writing as set forth below, CHMC may proceed with the presentation or publication. However, if Sponsor notifies CHMC in writing within such period that it has a reasonable belief that such presentation or publication would reveal Sponsor's Confidential Information or a potentially patentable invention for which patent applications are to be filed under Section 8, it will provide a written request to CHMC specifically identifying the information giving rise to the belief. CHMC will consider Sponsor's request in good faith. If it agrees with Sponsor, it will, as applicable, remove Sponsor's Confidential Information or not publish or present the information so identified by Sponsor 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 Sponsor, whichever occurs first. Sponsor will keep all submissions made by CHMC hereunder confidential in accordance with Section 6 until such time as CHMC or its affiliates or investigators make the applicable publication or presentation.

B. <u>Outside Activities</u>. Nothing in this Agreement will be construed to limit either party's right to independently develop products and processes or conduct and share the results of its own independent research without the use of the other party's Confidential Information. Moreover, nothing in this Agreement will preclude CHMC from entering into sponsored research agreements with third parties that may be related to, but are otherwise outside the scope of, the Research Program set forth on the Statement of Work, provided that it does not use Sponsor's Confidential Information. For purposes of this Agreement, all of the foregoing will be considered "<u>Outside Activities</u>."

8. PROGRAM INVENTIONS; OPTION.

A. Ownership. For purposes of this Agreement, "Program Inventions" means any invention(s) conceived and first actually or constructively reduced to practice during the Term in the course of, and directly arising from, the Research Program, solely or jointly by the PI or CHMC's other investigators participating in the Research Program. However, Program Inventions will not include any improvements to CHMC's Background Inventions or improvements to CHMC's Outside Activity Inventions unless such improvements are expressly specified to be developed and delivered under the Research Program Statement of Work. Title to all Program Inventions, and all patent applications, resulting patents, copyrights, trademarks, trade secrets or other intellectual property rights therein, will be and remain solely with CHMC. The parties do not intend that any of the foregoing be considered jointly created with Sponsor or any of its investigators. Sponsor agrees to execute and cause any of its employees and independent contractors to execute any additional assignments or other 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 Sponsor will sign or cause to be signed such documents and otherwise cooperate at no cost to CHMC.

B. <u>Invention Disclosures</u>. PI and any other CHMC investigators involved in the Research Program will report all Program Inventions to CHMC and will assign all of their right, title and interest in such Program Inventions to CHMC. CHMC will promptly make a written disclose of such Program Inventions to Sponsor (each an "<u>Invention Disclosure</u>"). All Invention Disclosures and any related information provided to Sponsor under this Section 8 will be part of CHMC's Confidential Information until the publication of such information by PI or until CHMC has provided Sponsor written verification that all desirable patent applications have been filed, whichever occurs first.

- C. Patent Filings. Sponsor will, within thirty (30) days after it receives the Invention Disclosure, notify CHMC in writing of all of the countries in which it is interested in having CHMC file patent applications with respect to the applicable Program Invention (the "Filing Request"). Failure by Sponsor to notify CHMC in a Filing Request of any particular country or countries within such thirty (30) day period will constitute Sponsor's decision that it is not interested in filing in such countries, in which case CHMC will be free to file and prosecute patent applications with respect to such Program Invention at its own expense in such countries and license the patent application and any resulting patent rights issuing therefrom in such countries to any other party and retain all proceeds therefrom. With respect to patent applications in countries requested by Sponsor in its Filing Requests, CHMC will use reasonable efforts to deliver to Sponsor drafts of all material submissions to patent authorities relating to such patent applications, and, to the extent feasible, to give Sponsor a reasonable opportunity to comment on such documents prior to their filing. Sponsor will provide any such comments promptly. CHMC will consider Sponsor's comments in good faith; however, the final decision with respect to such matter will remain with CHMC. All patent costs pertaining to any such patent applications, including all out-of-pocket, preparation, filing, prosecution, issuance and maintenance costs, will be borne by Sponsor.
- D. <u>Patents</u>. For purposes of this Agreement, "<u>Patents</u>" will mean the patent application(s) filed at Sponsor's expense and request under Section 8.C. above, together with any patents maturing therefrom 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 initial applications and they have the same priority date of such applications, but not including any additional or different claims), and the resulting patents therefrom.
- E. <u>Non-Exclusive License</u>. Sponsor will automatically have a perpetual, worldwide, non- exclusive, non-commercial, non-transferable, non-sublicenseable, royalty-free license to practice the Patents for Sponsor's internal non-commercial research purposes only.
- F. <u>Option</u>. Subject to Sponsor's fulfillment of its payment obligations under this Agreement, Sponsor will also have an option (the "<u>Option</u>") to negotiate a royalty-bearing, limited-term exclusive license (subject to third party rights, if any) under the Patents to develop, make, lease, sell, license, or otherwise distribute (in a designated field of use agreed to by the parties) products covered by at least a single claim of the Patents or developed, tested, screened or made in whole or part using a process covered by at least a single claim of the Patents.
- G. Exercise of Option. Sponsor may exercise its Option by providing written notice to CHMC within sixty (60) days from the date on which the Invention Disclosure was made to Sponsor (the "Option Period") that it is exercising the Option. Sponsor will be deemed to have declined to exercise the Option if it declines it in writing within the Option Period, or if it fails to provide notice of its exercise within the Option Period. The exercise of this Option is subject to the negotiation in good faith by the parties and execution of a license agreement with mutually acceptable terms and conditions (including, without limitation, with respect to royalties and other payments, due diligence obligations, field of use restrictions, limitations of liability and insurance obligations). The parties will endeavor to negotiate and execute the license agreement within six (6) months after exercise of the Option by Sponsor, although this period may be extended by mutual agreement of the parties. Neither party will be bound to any exclusive license obligations unless and until such license agreement is executed by both parties, and neither party will be liable for any failure to come to mutually agreeable terms within the above timeframe despite good faith negotiations, in which case CHMC will have the right to negotiate and enter into exclusive licenses to the Patents in the same field of use with third parties.

9. MATERIALS. CHMC will own all right, title and interest in any copyright protected materials (whether or not registered with the United States Copyright Office or other copyright authorities) first produced or composed during the Term during and as a result of the Research Program. If the parties execute a license agreement under Section 8,, then CHMC will grant to Sponsor a limited, royalty-free, non-transferable, non-sublicenseable, non-exclusive license to use such materials solely for Sponsor's own internal use in connection with the licensed Patents during the term of such license agreement. However, the foregoing license will not apply to any software or related documentation unless they are expressly specified to be developed and delivered under the Research Program Statement of Work. Nor will it apply to any improvements made to materials of CHMC that were in existence before the Research Program. The license to any copyright protected Biological Materials will be subject to Section 10 below.

10. BIOLOGICAL MATERIALS. In the event that CHMC develops any patented or unpatented biological or chemical materials during and as a result of the Research Program, such as, without limitation, chemical compounds, animal models, cell lines, cells, nucleic acids, receptors and reagents (collectively, "Biological Materials"), and the parties enter into a license agreement under Section 8 above, CHMC will grant Sponsor a limited, non-transferable, non-commercial, non-exclusive license to use such Biological Materials in connection with the license to the Patents through a separate written non-exclusive license agreement governing the ownership and usage rights of such Biological Materials and any progeny thereof and substances replicated or derived therefrom.

11. RESERVATION OF RIGHTS; GOVERNMENT RIGHTS.

A. <u>Reservation of Rights</u>. Notwithstanding the execution of any license agreement under Section 8, CHMC reserves on behalf of itself and its affiliates and investigators the right to utilize any Program Inventions and Patents for clinical and non-clinical non-commercial research, testing, educational or patient care purposes and to license them to other non-profit organizations at no charge for their own non-commercial research, testing, educational or patient care purposes, provided that they have agreed in writing to limit their use in the applicable countries and field of use to such non-commercial purposes.

B. <u>Government Rights</u>. If federal, state or local funding supports the Program Invention, Sponsor's license may be subject to the rights, conditions and limitations imposed by U.S. federal and/or state or local law, including, without limitation, a royalty-free non-exclusive license granted to the U.S. government and other rights under 35 U.S.C. Section 200 *et. seq.* and any regulations pertaining thereto (or any successor statutes or regulations), and the requirement that any Product produced for sale in the United States will be manufactured substantially in the United States. If any term of this Agreement fails to conform with the foregoing statutes and regulations, such term will be unenforceable and subject to the severability provisions in Section 23.

12. BACKGROUND INVENTIONS AND INVENTIONS FROM OUTSIDE ACTIVITIES. The parties acknowledge and agree that all right, title and interest in and to any proprietary inventions or technology conceived of or reduced to practice by the respective parties either (a) prior to the Effective Date ("Background Inventions") or (b) pursuant to any Outside Activities ("Outside Activity Inventions"), and all present and future patents, copyrights, trade secrets or other intellectual property rights in any of the foregoing, are and will remain the sole and exclusive property of CHMC or Sponsor, respectively, and that neither party will have any rights or licenses whatsoever, whether by implication, estoppel or otherwise, to the other party's Background Inventions or Outside Activity Inventions.

13. INDEMNIFICATION; INSURANCE.

A. <u>Indemnification</u>. Sponsor will, at its sole expense, defend CHMC and its affiliates, and its and their agents, directors, trustees, officers, contractors and employees (or anyone of them) against all claims, suits, actions, demands, judgments, or investigations asserted by third parties (both governmental and non-governmental), and will indemnify and hold them harmless from and against any and all losses, costs, damages, fees, liabilities, penalties or expenses (including, without limitation, reasonable attorneys' fees) assessed, awarded or incurred under any theory of liability, including without limitation, tort, warranty or strict liability, arising out of or related to this Agreement, the Research Program, Patents, Program Inventions, Biological Materials, or any products or processes used or sold pursuant to any license granted under this Agreement. However, the foregoing will not apply to the extent that any of the foregoing are caused by the gross negligence or willful misconduct of CHMC.

B. <u>Insurance</u>. Sponsor will, throughout the Term and for three (3) years thereafter, maintain in force at its sole cost and expense, with reputable insurance companies, insurance in an amount and type reasonably sufficient to protect against liability hereunder, but in no event less than at least One Million Dollars (\$1,000,000) per occurrence and Three Million Dollars (\$3,000,000) 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. CHMC will have the right from time to request the appropriate certificates of insurance from Sponsor for the purpose of ascertaining the sufficiency of such coverage. The amounts of insurance coverage required herein will not be construed as creating any limitation on Sponsor's indemnification obligations above.

14. WARRANTY DISCLAIMER. Nothing in this Agreement will be construed as a warranty or representation that any Program Inventions, Patents or anything made, used, sold or otherwise disposed of under any license entered into by the parties under Section 8 is or will be free from infringement of patents, copyrights, trade secrets or other intellectual property of third parties. Moreover, Sponsor understands that the research is experimental in nature and that its outcome is inherently uncertain and unpredictable. CHMC MAKES NO, AND HAS NOT MADE ANY, REPRESENTATIONS OR WARRANTIES OF ANY KIND, EITHER EXPRESS OR IMPLIED, INCLUDING WITHOUT LIMITATION, ANY WARRANTY OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE OR ANY OTHER WARRANTY, EXPRESS OR IMPLIED, AND ASSUMES NO RESPONSIBILITIES WHATSOEVER WITH RESPECT TO, THE RESEARCH PROGRAM, PATENTS, PROGRAM INVENTIONS, BIOLOGICAL MATERIALS, OR ANY OTHER MATERIALS FURNISHED BY CHMC UNDER THIS AGREEMENT, OR THE SALE OR OTHER DISPOSITION OF PRODUCTS OR PROCESSES INCORPORATING ANY OF THE FOREGOING. THE FOREGOING ARE ALL PROVIDED AS IS.

15. 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 RESEARCH PROGRAM, PATENTS, PROGRAM INVENTIONS, BIOLOGICAL MATERIALS, OR ANY OTHER MATERIALS FURNISHED BY CHMC UNDER THIS AGREEMENT, OR THE SALE OR OTHER DISPOSITION OF PRODUCTS OR PROCESSES INCORPORATING ANY OF THE FOREGOING, INCLUDING BUT NOT LIMITED TO DAMAGES MEASURING LOST PROFITS, GOODWILL OR BUSINESS OPPORTUNITIES, EVEN IF ADVISED IN ADVANCE OF THE POSSIBILITY OF SUCH DAMAGES. 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 RESEARCH PROGRAM, THE RESULTS THEREOF, PROGRAM INVENTIONS, PATENTS AND THE BIOLOGICAL MATERIALS EXCEED THE TOTAL AMOUNT OF COSTS ACTUALLY REIMBURSED UNDER SECTION 4.

16. ASSIGNMENT; SUBLICENSING. This Agreement will be binding upon and inure to the benefit of the parties hereto and their permitted successors and assigns. This Agreement will not be assignable, sublicenseable or otherwise transferable in whole or part by either party, whether by contract, change of control, operation of law or otherwise (other than the right to receive payments), without the prior written consent of the other party, and any attempted transfer without such consent will be void and of no effect.

17. 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 patent, trademark, copyright and other applicable federal laws of the United States of America, and CHMC and Sponsor submit to the exclusive personal 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.

18. GOVERNING LANGUAGE. In the event that a translation of this Agreement is prepared and signed by the parties for the convenience of Sponsor, this English language version will be the official version and will govern if there is a conflict between the two. All notices and other correspondence between the parties will also be provided in English.

19. EXPORT CONTROLS. It is understood that this Agreement is subject to United States laws and regulations controlling the export of technical data, computer software, laboratory prototypes, and other commodities, and that CHMC's obligations hereunder are contingent upon compliance with all such export laws and regulations (including the Arms Export Control Act, as amended, and the Export Administration Act of 1979). The transfer of certain technical data and commodities (including, without limitation, Biological Materials and related information) may require a license from the applicable agency of the United States Government and/or written assurances by Sponsor that Sponsor will not re-export data or commodities to certain foreign countries without prior approval of the cognizant government agency. While CHMC agrees to reasonably cooperate with Sponsor in Sponsor's efforts to secure any license which the applicable agency deems necessary in connection with this Agreement, CHMC cannot guarantee that such licenses will be granted. In any event, Sponsor specifically agrees not to export or re-export any information and/or technical data and/or products in violation of any applicable laws and/or regulations. Sponsor 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. Sponsor 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.

20. FORCE MAJEURE. CHMC will not be responsible to Sponsor for any delay or failure to perform any of the obligations imposed by this Agreement occasioned by fire, flood, explosion, lightning, windstorm, earthquake, subsidence of soil, failure or destruction, in whole or in part, of machinery or equipment or failure of supply of materials, discontinuity in the supply of power, governmental interference, civil commotion, riot, war, strikes, labor disturbance, transportation difficulties, labor shortage, acts of God or any other cause beyond the reasonable control of CHMC (a "Force Majeure Event"). Upon any such Force Majeure Event, CHMC will advise Sponsor of anticipated duration of the non-performance and will take reasonable steps to resume performance when the Force Majeure Agreement has ended.

21. NOTICES. All notices to be given hereunder will be in writing and personally delivered or sent by postage pre-paid first class mail, airmail 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 addresses first set forth above, or such other address as a party will designate in writing for such purpose. All notices to CHMC will be sent to the attention of the Legal Department, with a copy to Director of Portfolio Management, Innovation Ventures, ML 7032. All notices to Company will be sent to the attention of:

Erin Henderson Chief Business Officer Blue Water Vaccines, Inc. 201 E. Fifth Street, Suite 1900 Cincinnati, Ohio 45202 ehenderson@bluewatervaccines.com

Invoices will be sent to:

Blue Water Vaccines, Inc. Accounts Payable 201 E. Fifth Street, Suite 1900 Cincinnati, Ohio 45202 brose@bluewatervaccines.com

- **22. ENTIRE AGREEMENT; HEADINGS; JOINT DRAFTING.** Except as otherwise expressly specified herein, this Agreement, together with its Exhibits, which are hereby incorporated by reference, embodies the entire understanding between CHMC and Sponsor with respect to its subject matter, and any prior or contemporaneous representations, either oral or written, are hereby superseded. No amendments or changes to this Agreement, including without limitation, changes in the Statement of Work, will be effective unless made in writing and signed by authorized representatives of the parties. 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.
- **23. 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, 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 in accordance with the parties' initial intent, and the parties agree that such substitute provision will be as enforceable as if set forth initially in this Agreement.
- **24. WAIVER.** The waiver by either party of a breach of any provisions of this Agreement by the other party must be in written form and signed by the party against whom it is charged and will not be construed as a waiver of any succeeding breach of the same or any other provision.
- **25. INDEPENDENT CONTRACTORS.** The relationship between CHMC and Sponsor 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.
- **26. COUNTERPARTS.** This Agreement may be executed in one or more counterparts, each of which will be deemed to be an original copy of the Agreement, and all of which, when taken together, will be deemed to constitute one and the same Agreement. Signatures to this Agreement transmitted by fax, by electronic mail in "portable document format" (".pdf"), or by any other electronic means intended to preserve the original graphic and pictorial appearance of the Agreement, will have the same effect as physical delivery of the paper document bearing the original signature.

IN WITNESS WHEREOF, the parties have executed this Agreement as of the Effective Date.

Children's Hospital Medical Center

SPONSOR

By /s/ Abram S. Gordon

Name: Abram S. Gordon
Title: Vice President,

Innovation Ventures

By /s/ Joseph Hernandez

Name: Joseph Hernandez

Title: _CEO

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Exhibit A

Research Plan/ Scope of Work

P24 nanoparticles

• Three OREO sequences will be cloned into each of the three presentation loops for one P24 nanoparticle construct (P24-3o)

DNA sequences encoding the three P- OREO fusion proteins will be synthesized *de* novo via a commercial company with codon optimization for *E. coli*. We will typically add a short liker sequence, usually a GGG (three glycines) to each end of the OREO sequences to provide certain flexibility for better success likelihood.

• One additional OREO sequence will be cloned into a second VLP construct (P24-1o).

DNA sequences encoding the one P-OREO fusion proteins will be synthesized *de* novo with codon optimization for *E. coli*. Similar liker sequence will be added (see above).

• Blue Water will provide the DNA sequences for each of the four OREO peptides and indicate which of the three sequences will be used to create P24-1o.

Blue Water provides the Wild type H11 HA sequences and the sequences of FIVE OREOs

Oreo sequences:

Three of these Oreo will be selected to be inserted to the three surface loops of the P24 particle.

• The P24-3o and P24-1o nanoparticles will be expressed in *E. coli* and purified by techniques previously developed by CCHMC.

Based on our previous success experiences, both P-3o and P-1o fusion proteins will be expressed via the *E. coli* system as GST-fusion proteins. The proteins will be purified using the GST-binding resin. The GST-tag will be removed from the target proteins to allow self-formation of the P24-3o and P24-1o particles.

• The P24-3o and P24-1o nanoparticles will be characterized using techniques (gel filtration, EM, etc.) as determined by CCHMC.

The P24-30 and P24-10 nanoparticle formation and their efficiencies will be shown by gel filtration chromatography and EM observation.

• A group of 20 mice will be immunized with a formulation to be discussed on days 0 and day 21. Animals will be bled on day 35. *NOTE: We opted for 20 animals per test group to ensure sufficient sera for analysis.*

Three groups of Balb/C mice:

Group 1: P24-3o (n=20)

Group 2: P24-1o (n=20)

Group 3: wild type P24 w/o OREO as a control (n=20)

Mice will be immunized twice on days 0 and day 21. Formulation, dose, and route will be determined by Blue Water Vaccines.

To be able to measure the OREO peptide-specific antibody responses, we will need to synthesize the corresponding OREO peptides and conjugate them to KLH, respectively, as capture antigens to be used in antibody detecting ELISAs.

S60 nanoparticles

• One OREO sequence will be cloned into the H7 "scaffold" protein fragment previously used by CCHMC. Blue Water will provide the OREO sequence and location for insertion into the H7 fragment.

This construct is referred as S60-H7-HA1-OREO. DNA sequences encoding the S-H7- HA1-OREO fusion proteins will be synthesized *de novo* via a commercial company with codon optimization for *E. coli*. The DNA fragment will then be cloned into our plasmid to be the expression construct.

• The same OREO sequence cloned into H7 will also be cloned into H11. Blue Water will provide the H11 DNA sequence and location for insertion into the H11 fragment.

This construct is referred as S60-H11-HA1-OREO. DNA sequences encoding the S-H11- HA1-OREO fusion proteins will be synthesized *de novo* with codon optimization for *E. coli*. The DNA fragment will then be cloned into our plasmid to be the expression construct.

 Both S60-H7-HA1-OREO and S60-H11-HA1-OREO proteins will be expressed in *E. coli* and purified by techniques previously developed by CCHMC. Both S60-H7-HA1-OREO and S60-H11-HA1-OREO proteins will be first expressed via the E. coli system as His-tagged proteins and purified using Hisx6-binding resin. His-tag will not be removed from the final product. For the S60-H7-HA1-OREO we are confident that soluble protein will be made directly. For the S60-H11-HA1-OREO, we may or may not be able to make soluble protein directly. If soluble protein cannot be made directly, a denature/renature approach will be used.

Blue Water provides the Wild type H11 HA sequences and the sequences of FIVE OREOs

Oreo sequences:

Two OREOs will be used for S60 particle presentation, one will be used on the H7 scaffold and one will used on the H11 scaffold.

 Both S60-H7-HA1-OREO and S60-H11-HA1-OREO will be characterized using techniques (gel filtration, EM, etc.) as determined by CCHMC.

Both generated S60-H7-HA1-OREO and S60-H11-HA1-OREO proteins will be characterized using by gel filtration chromatography and EM observation. In addition, hemagglutination test can also be performed to further prove the structural and functional integrity of the S60-H7-HA1-OREO and S60-H11-HA1-OREO particles.

• A group of 20 mice will be immunized with a formulation to be discussed using the H7 construct on day 0 and the H11 construct on day 21. Animals will be bled on day 35.

Two groups of Balb/C mice:

Group 1: n=20, immunization at day 0 with the S60-H7-HA1-OREO particle, and day 21 with the S60-H11-HA1-OREO H11 construct.

Group 2: n=20, immunized first with wild type S60-H7-HA1 particle w/o OREO and followed by a second immunization with wild-type S60-H11-HA1 w/o OREO.

Formulation, dose, and route will be determined by Blue Water Vaccines.

Exhibit B

Budget

Budget and its justification

Laboratory supplies and reagents: \$ 19,000

The requested fund will be used to purchase various supplies and reagents that will be necessary for the proposed work, including 1) constructions of various plasmids, production and evaluation of recombinant P24 and S60-HA1 fusion proteins with various OREO sequences, 2) characterization of the nanoparticle formation and their structural integrity, 3) immunization of mice with the nanoparticles and control immunogens, and 4) determination of OREO-specific antibody titers of the mouse sera after immunization of the nanoparticles and controls.

Kits and reagent: Plasmid DNA isolation kits (\$300/kit, 250 preps), DNA gel extraction kit (\$100/kit, 50 preps), Talon his-tag purification resin (\$300/25ml), GST-binding resin (\$300/25ml), size-exclusion columns (\$2400/each), endotoxin detection and removal system (\$250/kit); high-fidelity polymerase, restriction enzymes, secondary antibodies for EIAs, other reagents/plastic wares for experiments of molecular biology and *E. coli* cultures.

Other expenses:

DNA synthesis: \$ 4,000

Funds requested will be used to pay for synthesis of 1) DNA fragments encoding the P domain protein with insertions of three given OREO sequences in the surface loops; and 2) DNA fragments encoding the S domain-HA1 (H7 and H11 type) fusion proteins w/o and with given OREO to replace the wild type ones. These DNA fragments are for constructions of various expression constructs to produce corresponding recombinant fusion proteins and their nanoparticles. The DNA syntheses will be conducted through a commercial company.

Peptide syntheses and KLH conjugations: \$ 3,000

Funds requested will be used to pay for synthesis of the given OREO peptides. These peptides will then be conjugate to KLH (keyhole limpet hemocyanin) and purified for polyvalent presentations of the OREO peptides. These conjugates will be used as capture antigens in ELISA assays to determine the OREO-specific antibody titers. These will be done through a commercial company.

Animal purchase and housing: \$ 6,000

Funds requested will be used to pay for purchasing mice, as well as their housing cost at the animal facility at CCHMC. These mice are for immunization study to determine the OREO-specific immune responses.

Electron microcopy core: \$ 3000

Funds requested will be used to pay for the service at the electron microcopy core facility at CCHMC. This is to evaluate the P24-OREO and S60-HA1(H7/H11)-nanoparticle formation.

Personnel effort: \$ 120,789

- 1. **Ming Tan**, PhD, the PI (effort=3.6 calendar months), will be responsible for the overall research design and performance of this work. In addition, Dr. Tan will perform gel filtration chromatography and electron microscopy to evaluate the nanoparticle formation. He will help the team members for data analyses, interpretations, and trouble-shootings. Dr. Tan will be responsible for summarizing research data and preparing the final progress reports of this work.
- 2. **Ming Xia**, PhD, a research associate (effort=6.0 calendar months), will be responsible for daily experiment performance, including 1) plasmid construction and protein production of individual P24, and S60-HA1 nanoparticles displaying the given OREOs, 2) quality characterization of the P24-OREO and S60-HA1-OREO nanoparticles; 3) immunization of mice with the nanoparticle and various controls, and 4) assessment of the immune responses of the OREO. He will work with Pengwei Huang to complete these tasks.
- 3. **Pengwei Huang**, PhD, a research associate (effort=4.2 calendar months), will be working to together with Ming Xia to complete the listed task above.

Total direct cost: \$155,789

Blue Water Vaccines Announces Signing of Sponsored Research Agreement with Cincinnati Children's Hospital Medical Center for S&P Vaccine Platform Development

CINCINNATI, July 20, 2022 (GLOBE NEWSWIRE) -- Blue Water Vaccines Inc. ("BWV" or "Blue Water Vaccines" or "the Company"), a biopharmaceutical company developing transformational vaccines to address significant global health challenges, today announced that the Company has entered into a Sponsored Research Agreement (the "SRA") with Cincinnati Children's Hospital Medical Center ("Cincinnati Children's") to explore vaccine development of its norovirus shell and protrusion (S&P) platform for multiple diseases.

In July 2021, the Company entered an exclusive, global licensing agreement with Cincinnati Children's to develop vaccines for multiple diseases using the medical center's virus-like particle (VLP) vaccine platform. Currently, the platform is being utilized to develop BWV-301 for gastroenteritis caused by norovirus or rotavirus. Through the SRA, BWV will further fund research into this platform's versatility across other diseases, including influenza and Alzheimer's disease.

In a recent publication in *Nano Research*, titled "Bioengineered psuedovirus nanoparticles displaying the HA1 antigens of influenza viruses for enhanced immunogenicity," Cincinnati Children's researchers hypothesized that this platform might represent a method to create novel influenza vaccines. The SRA initiates the integration of the epitopes of limited variability identified at The University of Oxford into this S&P platform for vaccine development.

In addition, the SRA funds Cincinnati Children's research analyzing the applicability of this platform to develop a vaccine for Alzheimer's disease. Preliminary research indicates the potential to develop a vaccine to target and inactivate amyloid-beta, which can accumulate and form plaques commonly associated with Alzheimer's disease.

"This agreement is an important step toward developing vaccines against multiple diseases that affect millions of individuals each year," said Ming Tan, Ph.D., Associate Professor in the Division of Infectious Diseases and principal investigator of the study at Cincinnati Children's. "Through this agreement and in collaboration with BWV, we can continue our research and work toward development of beneficial vaccines."

Tan has a financial interest in the virus-like particle (VLP) vaccine platform technology that Cincinnati Children's licensed to Blue Water Vaccines.

"We are very excited to continue our collaboration with Cincinnati Children's and fund this research," said Joseph Hernandez, Chairman and Chief Executive Officer of Blue Water Vaccines. "Research from Cincinnati Children's has shown great promise for this platform, and we look forward to continuing this relationship to address significant public health challenges through effective vaccines."

Gastroenteritis, influenza, and Alzheimer's disease all represent significant global health challenges in illness and mortality, as well as associated economic loss. Efficacious vaccine intervention may prove an effective public health intervention and address such losses on a global scale.

About Blue Water Vaccines

Blue Water Vaccines Inc. is a biopharmaceutical company focused on developing transformational vaccines to address significant health challenges globally. Headquartered in Cincinnati, OH, the company holds the rights to proprietary technology developed at the University of Oxford, Cincinnati Children's Hospital Medical Center, and St. Jude Children's Hospital. The company is developing a universal flu vaccine that will provide protection from all virulent strains in addition to licensing a novel norovirus (NoV) S&P nanoparticle versatile virus-like particle (VLP) vaccine platform from Cincinnati Children's to develop vaccines for multiple infectious diseases, including norovirus/rotavirus and malaria, among others. Additionally, Blue Water Vaccines is developing a Streptococcus pneumoniae (pneumococcus) vaccine candidate, designed to specifically prevent the highly infectious middle ear infections, known as Acute Otitis Media (AOM), in children. For more information, visit www.bluewatervaccines.com.

About Cincinnati Children's

Cincinnati Children's ranks among the top three in the nation in *U.S. News & World Report's* 2022-23 listing of Best Children's Hospitals. A nonprofit, academic medical center established in 1883, Cincinnati Children's is also one of the top three recipients of pediatric research grants from the National Institutes of Health. The medical center is internationally recognized for improving child health and transforming delivery of care through fully integrated, globally recognized research, education, and innovation. Additional information about technologies developed at Cincinnati Children's may be found at Innovation.CincinnatiChildrens.org

Forward-Looking Statements

Certain statements in this press release are forward-looking within the meaning of the Private Securities Litigation Reform Act of 1995. These statements may be identified by the use of forward-looking words such as "anticipate," "believe," "forecast," "estimate," "expect," and "intend," among others. These forward-looking statements are based on BWV's current expectations and actual results could differ materially. There are a number of factors that could cause actual events to differ materially from those indicated by such forward-looking statements. These factors include, but are not limited to, risks related to the development of BWV's vaccine candidates; the failure to obtain FDA clearances or approvals and noncompliance with FDA regulations; delays and uncertainties caused by the global COVID-19 pandemic; risks related to the timing and progress of clinical development of our product candidates; our need for additional financing; uncertainties of patent protection and litigation; uncertainties of government or third party payor reimbursement; limited research and development efforts and dependence upon third parties; and substantial competition. As with any vaccine under development, there are significant risks in the development, regulatory approval and commercialization of new products. BWV does not undertake an obligation to update or revise any forward-looking statement. Investors should read the risk factors set forth in BWV's Annual Report on Form 10-K for the fiscal year ended December 31, 2021, filed with the Securities and Exchange Commission (the "SEC") on March 31, 2022, and periodic reports filed with the SEC on or after the date thereof. All of BWV's forward-looking statements are expressly qualified by all such risk factors and other cautionary statements. The information set forth herein speaks only as of the date thereof.

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