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): June 28, 2023

Blue Water Biotech, Inc.
(Exact name of registrant as specified in its charter)

Delaware	**001-41294**	**83-2262816**
(State or other Jurisdiction of Incorporation)	(Commission File Number)	(IRS Employer Identification No.)

201 E. Fifth Street, Suite 1900 Cincinnati, Ohio	**45202**
(Address of Principal Executive Offices)	(Zip Code)

Registrant's telephone number, including area code: **(513) 620-4101**

(Former name or former address, if changed since last report.)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

☐ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

☐ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

☐ Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

☐ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Securities registered pursuant to Section 12(b) of the Act:

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

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

Emerging growth company ☒

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

Item 8.01 Other Events.

On June 28, 2023, Blue Water Biotech, Inc., a Delaware corporation (the "Company"), issued a press release announcing preliminary preclinical data supporting the use of its norovirus shell and protrusion virus-like particle platform to develop a novel monkeypox vaccine candidate (the "Press Release"). The Press Release is attached hereto as Exhibit 99.1 and incorporated herein by reference.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits

99.1	Press Release, dated June 28, 2023
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.

Blue Water Biotech, Inc.

Date: June 28, 2023

By: /s/ Joseph Hernandez

Joseph Hernandez
Chief Executive Officer

Exhibit 99.1

Blue Water Biotech Announces Preclinical Data Supporting Immunogenicity of Novel Monkeypox Vaccine Utilizing Norovirus Virus-Like Particle Platform

CINCINNATI, OH, June 28, 2023 - Blue Water Biotech, Inc. ("Blue Water" or the "Company") (Nasdaq: BWV), a biotechnology and pharmaceutical company spanning multiple sectors, today announced preliminary preclinical data supporting the use of its norovirus shell and protrusion ("S&P") virus-like particle ("VLP") platform to develop a novel monkeypox vaccine candidate.

In August 2022, Blue Water announced plans to explore the development of its novel monkeypox vaccine candidate by presenting monkeypox antigens within the S&P platform. Following successful integration of selected antigens into the platform, mice were immunized with the vaccine candidate and analyzed for antibody levels in the blood. Initial data show that mice were able to generate an immune response following vaccination and antibodies were able to neutralize the vaccinia virus. Vaccinia, the virus responsible for smallpox disease, belongs to the same family as monkeypox virus and has shown high levels of cross-reactivity with monkeypox.

"We are thrilled to announce this exciting initial step in development of our monkeypox vaccine candidate," said Joseph Hernandez, Chairman and Chief Executive Officer of Blue Water. "This platform has shown wide versatility across multiple infectious diseases, including influenza, norovirus, rotavirus, among others, and we are excited to continue to work towards a next generation monkeypox vaccine. While we are heavily focused on the commercialization of our recently acquired FDA approved assets, our development programs continue with success, highlighted by this new data."

"This data is certainly promising for future development of this VLP vaccine candidate," said Ali Fattom, Ph.D., Head of Science and Discovery of Blue Water. "Current vaccines utilize the entire vaccinia virus, while our approach selects targeted antigens hypothesized to generate robust immune responses and by partnering this with our VLP platform, we believe we will be able to create a novel, effective vaccine to protect individuals around the world. Armed with information from this preliminary study, we can confidently move forward in preclinical development and initiate studies to show protective immunity in relevant animal models, with the ultimate goal of bringing this candidate to clinical trials and commercialization."

In July 2021, Blue Water entered an exclusive, global licensing agreement with Cincinnati Children's Hospital Medical Center to develop vaccines for multiple infectious diseases utilizing the latter's novel VLP vaccine platform. The platform leverages norovirus capsid proteins to present foreign antigens for immune enhancement.

According to the World Health Organization, monkeypox is a virus transmitted to humans from animals, with clinical symptoms like those seen in smallpox patients. Human-to-human transmission can result from close contact with respiratory secretions, skin lesions of an infected person, or recently contaminated objects. According to the Centers for Disease Control and Prevention ("CDC"), the 2022 outbreak of monkeypox resulted in over 88,000 cases across 111 locations, and in May 2023, the CDC reported a potential risk for 12 confirmed monkeypox cases in the Chicago area. There are two vaccines approved for prevention of monkeypox disease in the United States, but limited availability of either vaccine resulted in increasing cases within the United States and globally during the 2022 outbreak.

About Blue Water Biotech

Blue Water Biotech, Inc. is a biological and pharmaceutical technology company focused on developing and providing transformational therapies to address significant health challenges globally. Headquartered in Cincinnati, OH, the Company owns ENTADFI®, an FDA-approved, once daily pill that combines finasteride and tadalafil for the treatment of benign prostatic hyperplasia. This combination allows men to receive treatment for their symptoms of benign prostatic hyperplasia without the negative sexual side effects typically seen in patients on finasteride alone. The Company also has a robust vaccine pipeline. Blue Water holds the rights to proprietary technology developed at the University of Oxford, Cincinnati Children's Hospital Medical Center, St. Jude Children's Hospital, and The University of Texas Health Science Center at San Antonio. Blue Water is developing a Streptococcus pneumoniae vaccine candidate, designed to specifically prevent highly infectious middle ear infections, known as AOM, in children, and prevention of pneumonia in the elderly. The Company is also developing a universal flu vaccine that will provide protection from all virulent strains in addition to licensing a novel norovirus S&P nanoparticle versatile virus-like particle vaccine platform from Cincinnati Children's to develop vaccines for multiple infectious diseases, including Marburg and monkeypox, among others. Additionally, the Company is developing a Chlamydia vaccine candidate with UT Health Science Center San Antonio to prevent infection and reduce the need for antibiotic treatment associated with contracting Chlamydia disease. For more information about Blue Water, visit www.bwbioinc.com.

Cautionary Note Regarding 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 (including, without limitation, the anticipated benefits of the preclinical data described herein and the results of future preclinical or clinical studies of the vaccine candidate described herein) are based on Blue Water'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 Blue Water's ability to realize the benefits of its acquisitions of ENTADFI®, ZONTIVITY®, OTOVEL®, CETRAXAL®, CONJUPRI®, TREZIX™ and NALFON®; risks related to Blue Water's ability to expand its business scope, commercialize ENTADFI® and integrate the assets and commercial operations being acquired from WraSer into Blue Water's business; risks related to Blue Water's ability to attract, hire and retain skilled personnel and establish an effective sales team; risks related to Blue Water's ability to enter into a definitive agreement with IQVIA and optimize its collaboration with IQVIA; risks related to the development of Blue Water'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. Blue Water does not undertake an obligation to update or revise any forward-looking statement. Investors should read the risk factors set forth in Blue Water's Annual Report on Form 10-K, filed with the Securities and Exchange Commission (the "SEC") on March 9, 2023 and periodic reports filed with the SEC on or after the date thereof. All of Blue Water'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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