

**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): November 10, 2022

Blue Water Vaccines Inc.

(Exact name of registrant as specified in its charter)

Delaware

(State or other Jurisdiction
of Incorporation)

001-41294

(Commission File Number)

83-2262816

(IRS Employer
Identification No.)

201 E. Fifth Street, Suite 1900 Cincinnati, Ohio

(Address of Principal Executive Offices)

45202

(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 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 7.01 Regulation FD Disclosure.

On November 10, 2022, the Company issued a press release reporting its third quarter 2022 financial results and recent business highlights and announcing a 5 million shares repurchase program.

The full text of the press release is furnished as Exhibit 99.1 to this Form 8-K and is incorporated by reference in this Item 7.01.

The foregoing (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 and 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

| | |
|------|--|
| 99.1 | Press Release, dated November 10, 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 duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

Date: November 10, 2022

Blue Water Vaccines Inc.

/s/ Joseph Hernandez

Joseph Hernandez
Chief Executive Officer

Blue Water Vaccines Reports Third Quarter 2022 Financial Results and Recent Business Highlights; Announces 5 Million Share Repurchase Program

- Closed private placement in August 2022, with net proceeds of approximately \$8.7 million
- Announced plans to evaluate efficacy of BWV-201 for protection against non-invasive pneumococcal pneumonia in children and adults
- Board of Directors authorized a 5 million share repurchase program in November 2022
- \$29.1 million in cash as of September 30, 2022

CINCINNATI, OH, November 14, 2022 – Blue Water Vaccines Inc. (“BWV” or “Blue Water Vaccines” or the “Company”), today announced its financial results for the third quarter ended September 30, 2022 and provided an update on recent business developments and progress. Blue Water Vaccines is a pre-clinical stage biotechnology company developing vaccines against multiple infectious diseases, including acute otitis media (AOM) and pneumonia from *Streptococcus pneumoniae* colonization, influenza, norovirus, and rotavirus.

“At this moment in time, we do not believe our current valuation reflects our recent performance or our long-term market potential and opportunity,” said Joseph Hernandez, Chairman and Chief Executive Officer of Blue Water Vaccines. “We have made important progress in the development of our programs in recent months, such as expanding the indication of our *Streptococcus pneumoniae* candidate to include pneumococcal pneumonia based on promising data in mice. This positive momentum, along with our strong cash position of \$29.1 million at the end of the third quarter that we believe can fund operations well into 2023, allows us to execute a share repurchase program while continuing to develop our pipeline towards clinical trials.”

Q3 2022 and Recent Corporate Developments

- On August 11, 2022, BWV closed a private placement with aggregate net cash proceeds of approximately \$8.7 million.
- On August 22, 2022, the Company announced the appointment of Simon Tarsh, seasoned financial consultant with experience in the life science industry, to its board of directors (the “Board”) at BWV’s annual meeting. Mr. Tarsh brings over 40 years of experience in the financial industry to the Company, both domestically within the United States and on a global scale.
- On November 8, 2022, the Company announced the appointment of Vuk Jeremić to its Board on November 4, 2022. Mr. Jeremić brings decades of experience in operational and strategy advisement on a global scale for both private and public companies.
- On November 9, 2022, the Board approved a share repurchase program to allow for the Company to repurchase up to 5 million shares, with discretion to management to make purchases subject to market conditions.

Q3 2022 and Recent Vaccine Candidate Developments

- On July 20, 2022, BWV announced the signing of a Sponsored Research Agreement with Cincinnati Children's Hospital Medical Center ("Cincinnati Children's") to explore multiple vaccine candidates using BWV's norovirus shell and protrusion platform. The platform is currently being utilized to develop BWV-301, a vaccine for protection against gastroenteritis caused by norovirus or rotavirus. Under this agreement, BWV will fund additional research into this platform's versatility across multiple additional diseases for vaccine candidate development.
- On August 17, 2022, BWV announced plans to explore the potential to develop a novel monkeypox vaccine candidate using its norovirus shell and protrusion platform virus-like particle platform. Currently available monkeypox vaccines utilize the entire virus to elicit an immune response, while BWV's approach will attempt to present select monkeypox antigens within the S&P platform to protect individuals from disease.
- On October 11, 2022, the Company announced plans to evaluate the ability of BWV-201, a live attenuated *Streptococcus pneumoniae* vaccine candidate, to protect individuals against non-invasive pneumococcal pneumonia in children and adults. Given BWV-201 is delivered intranasally, rather than intramuscularly like the current pneumococcal vaccines on the market, BWV-201 is designed to elicit mucosal immunity and protect against disease in the lungs.
- At the World Vaccine Congress Europe 2022 in Barcelona, Spain (the "World Vaccine Congress"), on October 13, 2022, the Company presented new data showing that mice vaccinated with BWV-201, after previous exposure to PCV13, showed significantly decreased colonization of *Streptococcus pneumoniae* in the lungs following challenge, indicating a potential for BWV-201 to provide strong protection against pneumonia. This data was generated at St. Jude Children's Research Hospital ("St. Jude") under a BWV-funded sponsored research agreement.
- Additionally, at the World Vaccine Congress, BWV presented new data supporting the presentation of antigens from additional AOM-causing pathogens on the surface of BWV-201, including *Haemophilus influenzae* and *Moraxella catarrhalis*. This new data, generated at St. Jude, showed that mice vaccinated intranasally with the new BWV-201 construct produced antibodies against both *Haemophilus influenzae* and *Moraxella catarrhalis*, as well as antibodies against different strains of *Streptococcus pneumoniae*.
- Since the second quarter of this year, BWV has presented company information at key investor and financial conferences, including H.C. Wainwright's 24th Annual Global Investment Conference in New York, NY, and LD Micro Main Event XV in Los Angeles, CA.
- In addition to participating in investment conferences, BWV management presented scientific data and updates on vaccine candidates at conferences around the world, including The Universal Influenza Vaccines 2022 Conference in Oxford, United Kingdom, as well as the World Vaccine Congress.

Q3 2022 Financial Highlights

- **Cash Position:** Cash was \$29.1 million as of September 30, 2022, as compared to \$1.9 million as of December 31, 2021. The increase was primarily due to the closing of BWV's initial public offering in February 2022, a private placement that closed on April 19, 2022, and a private placement that closed on August 11, 2022. The Company believes its cash and cash equivalents are sufficient to fund operations through at least through the end of Q3 2024.
- **Research and Development Expenses:** For the three months ended September 30, 2022, research and development expenses increased by approximately \$0.9 million compared to the same period in 2021. The increase was primarily attributable to an increase in employee compensation and benefits, including annual bonus compensation and stock-based compensation, and an increase in preclinical development activities, related primarily to BWV-201.
- **General and Administrative Expenses:** For the three months ended September 30, 2022, general and administrative expenses increased by approximately \$1.9 million compared to the same period in 2021. The increase was mainly due to an increase in employee and director compensation and benefits, including annual bonus compensation and stock-based compensation, an increase in audit, accounting, and legal services, increases in various business activities related to company growth and development such as entering into a new lease, travel, patents-related expenses, and business advisory services, an expense associated with an accrued loss contingency, and increases in other business activities related to now being a public company.
- **Other Income:** Other income relates to the change in fair value of the contingent warrant liability, which is comprised of the change in fair value of the contingent warrant liability from the April Private Placement and the contingent warrant liability incurred at the close of the August Private Placement during the three months ended September 30, 2022. There was no other income or expense during the three months ended September 30, 2021.
- **Net Loss:** Net loss was approximately \$3.9 million for the three months ended September 30, 2022, as compared to \$1.1 million for the same period in 2021. The increase is primarily due to research and development of preclinical vaccine candidate development, as well as an increase in G&A expenses associated with now being a public company.

BLUE WATER VACCINES INC.
Condensed Balance Sheets

| | September 30, 2022 | December 31, 2021 |
|--|-------------------------------|------------------------------|
| | <u>(Unaudited)</u> | <u></u> |
| ASSETS | | |
| Current assets | | |
| Cash | \$ 29,136,716 | \$ 1,928,474 |
| Prepaid expenses | 703,829 | 234,551 |
| Deferred offering costs | 176,304 | 757,646 |
| Receivable from related party | 34,673 | 152,524 |
| Total current assets | <u>30,051,522</u> | <u>3,073,195</u> |
| Prepaid expenses, long-term | 66,357 | - |
| Property and equipment, net | 15,934 | 11,502 |
| Deposit | 27,588 | - |
| Total assets | <u>\$ 30,161,401</u> | <u>\$ 3,084,697</u> |
| LIABILITIES AND STOCKHOLDERS' EQUITY | | |
| Current liabilities | | |
| Accounts payable | \$ 834,308 | \$ 582,605 |
| Accrued expenses | 3,555,013 | 1,055,515 |
| Contingent warrant liability | 42,056 | - |
| Total current liabilities | <u>4,431,377</u> | <u>1,638,120</u> |
| Commitments and Contingencies (see Note 7) | | |
| Stockholders' equity | | |
| Preferred stock, \$0.00001 par value, 10,000,000 shares authorized at September 30, 2022 and December 31, 2021 | - | - |
| Series Seed: 0 and 1,150,000 shares designated at September 30, 2022 and December 31, 2021, respectively; 0 and 1,146,138 shares issued and outstanding at September 30, 2022 and December 31, 2021, respectively; \$0 and \$15.4 million aggregate liquidation preference at September 30, 2022 and December 31, 2021, respectively | - | 11 |
| Common stock, \$0.00001 par value, 250,000,000 shares authorized at September 30, 2022 and December 31, 2021; 14,689,851 and 3,200,000 shares outstanding at September 30, 2022 and December 31, 2021, respectively | 147 | 32 |
| Additional paid-in-capital | 41,888,452 | 7,403,204 |
| Accumulated deficit | (16,158,575) | (5,956,670) |
| Total stockholders' equity | <u>25,730,024</u> | <u>1,446,577</u> |
| Total liabilities and stockholders' equity | <u>\$ 30,161,401</u> | <u>\$ 3,084,697</u> |

BLUE WATER VACCINES INC.
Condensed Statements of Operations
(Unaudited)

| | Three Months Ended September 30, 2022 | Three Months Ended September 30, 2021 | Nine Months Ended September 30, 2022 | Nine Months Ended September 30, 2021 |
|---|--|--|---|---|
| Operating expenses | | | | |
| General and administrative | \$ 2,694,254 | \$ 825,999 | \$ 7,311,243 | \$ 1,326,275 |
| Research and development | 1,175,480 | 269,925 | 2,924,037 | 887,704 |
| Total operating expenses | 3,869,734 | 1,095,924 | 10,235,280 | 2,213,979 |
| Loss from operations | <u>(3,869,734)</u> | <u>(1,095,924)</u> | <u>(10,235,280)</u> | <u>(2,213,979)</u> |
| Other income | | | | |
| Change in fair value of contingent warrant liability | (3,072) | — | (33,375) | — |
| Total other income | (3,072) | — | (33,375) | — |
| Net loss | \$ (3,866,662) | \$ (1,095,924) | \$ (10,201,905) | \$ (2,213,979) |
| Cumulative preferred stock dividends | — | 186,320 | 96,359 | 463,224 |
| Net loss applicable to common stockholders | <u>\$ (3,866,662)</u> | <u>\$ (1,282,244)</u> | <u>\$ (10,298,264)</u> | <u>\$ (2,677,203)</u> |
| Net loss per share attributable to common stockholders, basic and diluted | <u>\$ (0.27)</u> | <u>\$ (0.40)</u> | <u>\$ (0.94)</u> | <u>\$ (0.84)</u> |
| Weighted average number of common shares outstanding, basic and diluted | 14,338,379 | 3,200,000 | 10,949,265 | 3,200,000 |

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.

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 Registration Statement on Form S-1, filed with the Securities and Exchange Commission (the "SEC") on August 29, 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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