

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

FORM 10-Q

(Mark One)

QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the quarterly period ended September 30, 2022

OR

TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the transition period from _____ to _____

Commission File Number: 001-41294

Blue Water Vaccines Inc.

(Exact name of registrant as specified in its charter)

Delaware

(State or other jurisdiction of
incorporation or organization)

201 E. Fifth Street, Suite 1900
Cincinnati, OH

(Address of principal executive offices)

81-2262816

(I.R.S. Employer
Identification No.)

45202

(Zip Code)

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

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

Title of each class	Trading Symbol(s)	Name of exchange on which registered
Common stock, \$0.00001 par value	BWV	The Nasdaq Stock Market LLC

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

None

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes No

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or 15(d) of the Act. Yes No

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes No

Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T (§ 232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit such files). Yes No

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, a smaller reporting company, or an emerging growth company. See the definitions of "large accelerated filer," "accelerated filer," "smaller reporting company," and "emerging growth company" in Rule 12b-2 of the Exchange Act.

Large accelerated filer	<input type="checkbox"/>	Accelerated filer	<input type="checkbox"/>
Non-accelerated filer	<input checked="" type="checkbox"/>	Smaller reporting company	<input checked="" type="checkbox"/>
		Emerging growth company	<input checked="" type="checkbox"/>

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.

Indicate by check mark whether the registrant has filed a report on and attestation to its management's assessment of the effectiveness of its internal control over financial reporting under Section 404(b) of the Sarbanes-Oxley Act (15 U.S.C. 726(b)) by the registered public accounting firm that prepared or issued its audit report.

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Act). Yes No

As of November 14, 2022, the registrant had 15,474,957 shares of common stock, \$0.00001 par value per share, outstanding.

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CAUTIONARY NOTE REGARDING FORWARD-LOOKING STATEMENTS

This Quarterly Report on Form 10-Q (this “Report”) contains forward-looking statements that reflect our current expectations and views of future events. The forward-looking statements are contained principally in the sections entitled “Risk Factors” and “Management’s Discussion and Analysis of Financial Condition and Results of Operations.” Readers are cautioned that known and unknown risks, uncertainties and other factors, including those over which we may have no control and others listed in the “Risk Factors” section of this Report, may cause our actual results, performance or achievements to be materially different from those expressed or implied by the forward-looking statements.

In some cases, you can identify forward-looking statements by the words “may,” “might,” “will,” “could,” “would,” “should,” “expect,” “intend,” “plan,” “objective,” “anticipate,” “believe,” “estimate,” “predict,” “project,” “potential,” “continue” and “ongoing,” or the negative of these terms, or other comparable terminology intended to identify statements about the future, although not all forward-looking statements contain these words. These statements relate to future events or our future financial performance or condition and involve known and unknown risks, uncertainties and other factors that could cause our actual results, levels of activity, performance or achievement to differ materially from those expressed or implied by these forward-looking statements. These forward-looking statements include, but are not limited to, statements about:

- our projected financial position and estimated cash burn rate;
- our estimates regarding expenses, future revenues and capital requirements;
- our ability to continue as a going concern;
- our need to raise substantial additional capital to fund our operations;
- the success, cost and timing of our clinical trials;
- our ability to obtain the necessary regulatory approvals to market and commercialize our product candidates;
- the ultimate impact of the ongoing COVID-19 pandemic, or any other health epidemic, on our business, our clinical trials, our research programs, healthcare systems or the global economy as a whole;
- the potential that results of pre-clinical and clinical trials indicate our current product candidates or any future product candidates we may seek to develop are unsafe or ineffective;
- the results of market research conducted by us or others;
- our ability to obtain and maintain intellectual property protection for our current product candidates;
- our ability to protect our intellectual property rights and the potential for us to incur substantial costs from lawsuits to enforce or protect our intellectual property rights;
- the possibility that a third party may claim we or our third-party licensors have infringed, misappropriated or otherwise violated their intellectual property rights and that we may incur substantial costs and be required to devote substantial time defending against claims against us;
- our reliance on third parties;
- the success of competing therapies and products that are or become available;
- our ability to expand our organization to accommodate potential growth and our ability to retain and attract key personnel;
- the potential for us to incur substantial costs resulting from product liability lawsuits against us and the potential for these product liability lawsuits to cause us to limit our commercialization of our product candidates;
- market acceptance of our product candidates, the size and growth of the potential markets for our current product candidates and any future product candidates we may seek to develop, and our ability to serve those markets; and
- the successful development of our commercialization capabilities, including sales and marketing capabilities.

These forward-looking statements involve numerous risks and uncertainties. Although we believe that our expectations expressed in these forward-looking statements are reasonable, our expectations may later be found to be incorrect. Our actual results of operations or the results of other matters that we anticipate herein could be materially different from our expectations. Important risks and factors that could cause our actual results to be materially different from our expectations are generally set forth in “Risk Factors,” “Management’s Discussion and Analysis of Financial Condition and Results of Operations,” and other sections in this Report. You should thoroughly read this Report and the documents that we refer to with the understanding that our actual future results may be materially different from and worse than what we expect. We qualify all of our forward-looking statements by these cautionary statements.

The forward-looking statements made in this Report relate only to events or information as of the date on which the statements are made in this Report. Except as required by law, we undertake no obligation to update or revise publicly any forward-looking statements, whether as a result of new information, future events or otherwise, after the date on which the statements are made or to reflect the occurrence of unanticipated events. You should read this Report and the documents that we refer to in this Report and have filed as exhibits to this Report, completely and with the understanding that our actual future results may be materially different from what we expect.

PART I – FINANCIAL INFORMATION

Item 1. Financial Statements

**BLUE WATER VACCINES INC.
Condensed Balance Sheets**

	September 30, 2022	December 31, 2021
	(Unaudited)	
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	30,051,522	3,073,195
Prepaid expenses, long-term	66,357	—
Property and equipment, net	15,934	11,502
Deposit	27,588	—
Total assets	\$ 30,161,401	\$ 3,084,697
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	4,431,377	1,638,120
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	25,730,024	1,446,577
Total liabilities and stockholders' equity	\$ 30,161,401	\$ 3,084,697

The accompanying notes are an integral part of these condensed financial statements.

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	\$ (0.27)	\$ (0.40)	\$ (0.94)	\$ (0.84)
Weighted average number of common shares outstanding, basic and diluted	14,338,379	3,200,000	10,949,265	3,200,000

The accompanying notes are an integral part of these condensed financial statements.

BLUE WATER VACCINES INC.
Condensed Statements of Stockholders' Equity
(Unaudited)

	Preferred Stock		Common Stock		Additional Paid-in Capital	Accumulated Deficit	Total Stockholders' Equity
	Shares	Amount	Shares	Amount			
Balance at December 31, 2021	1,146,138	\$ 11	3,200,000	\$ 32	\$ 7,403,204	\$ (5,956,670)	\$ 1,446,577
Issuance of common stock in initial public offering, net of \$2.9 million of offering costs	—	—	2,222,222	22	17,138,818	—	17,138,840
Conversion of convertible preferred stock to common stock upon initial public offering	(1,146,138)	(11)	5,626,365	56	(45)	—	—
Stock-based compensation	—	—	—	—	19,332	—	19,332
Net loss	—	—	—	—	—	(2,070,661)	(2,070,661)
Balance at March 31, 2022	—	\$ —	11,048,587	\$ 110	\$ 24,561,309	\$ (8,027,331)	\$ 16,534,088
Issuance of common stock and warrants in private placement, net of \$1.1 million of offering costs	—	—	590,406	6	6,858,322	—	6,858,328
Exercise of pre-funded warrants	—	—	590,406	6	(6)	—	—
Stock-based compensation	—	—	—	—	1,447,127	—	1,447,127
Net loss	—	—	—	—	—	(4,264,582)	(4,264,582)
Balance at June 30, 2022	—	\$ —	12,229,399	\$ 122	\$ 32,866,752	\$ (12,291,913)	\$ 20,574,961
Issuance of common stock and warrants in private placement, net of \$2.2 million of offering costs	—	—	1,350,000	14	8,689,302	—	8,689,316
Exercise of stock options	—	—	165,452	2	1,653	—	1,655
Exercise of pre-funded warrants	—	—	945,000	9	936	—	945
Stock-based compensation	—	—	—	—	329,809	—	329,809
Net loss	—	—	—	—	—	(3,866,662)	(3,866,662)
Balance at September 30, 2022	—	\$ —	14,689,851	\$ 147	\$ 41,888,452	\$ (16,158,575)	\$ 25,730,024
	Preferred Stock		Common Stock		Additional Paid-in Capital	Accumulated Deficit	Total Stockholders' Equity
	Shares	Amount	Shares	Amount			
Balance at December 31, 2020	1,146,138	\$ 11	3,200,000	\$ 32	\$ 7,273,063	\$ (2,539,336)	\$ 4,733,770
Stock-based compensation	—	—	—	—	41,721	—	41,721
Net loss	—	—	—	—	—	(325,781)	(325,781)
Balance at March 31, 2021	1,146,138	\$ 11	3,200,000	\$ 32	\$ 7,314,784	\$ (2,865,117)	\$ 4,449,710
Stock-based compensation	—	—	—	—	34,924	—	34,924
Net loss	—	—	—	—	—	(792,274)	(792,274)
Balance at June 30, 2021	1,146,138	\$ 11	3,200,000	\$ 32	\$ 7,349,708	\$ (3,657,391)	\$ 3,692,360
Stock-based compensation	—	—	—	—	29,308	—	29,308

Net loss	—	—	—	—	—	(1,095,924)	(1,095,924)
Balance at September 30, 2021	<u>1,146,138</u>	<u>\$ 11</u>	<u>3,200,000</u>	<u>\$ 32</u>	<u>\$ 7,379,016</u>	<u>\$ (4,753,315)</u>	<u>\$ 2,625,744</u>

The accompanying notes are an integral part of these condensed financial statements.

BLUE WATER VACCINES INC.
Condensed Statements of Cash Flows
(Unaudited)

	Nine Months Ended September 30, 2022	Nine Months Ended September 30, 2021
Cash flows from operating activities		
Net loss	\$ (10,201,905)	\$ (2,213,979)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation expense	4,906	3,737
Stock-based compensation	1,796,268	105,953
Change in fair value of contingent warrant liability	(33,375)	—
Changes in operating assets and liabilities:		
Prepaid expenses	(469,278)	(18,263)
Receivable from related party	(22,149)	(22,338)
Prepaid expenses, long-term	(66,357)	138,700
Deposit	(27,588)	15,000
Accrued expenses	2,760,734	496,113
Accounts payable	361,103	134,888
Deferred rent	—	(9,642)
Net cash used in operating activities	<u>(5,897,641)</u>	<u>(1,369,831)</u>
Cash flows from investing activities		
Purchase of property and equipment	(9,339)	—
Net cash used in investing activities	<u>(9,339)</u>	<u>—</u>
Cash flows from financing activities		
Payment of deferred offering costs	(51,304)	(196,975)
Proceeds from issuance of common stock in initial public offering, net of underwriting discount	18,400,000	—
Payments of initial public offering costs	(926,972)	—
Proceeds from issuance of common stock and warrants in private placements, net of placement agent discount	16,468,123	—
Payments of private placement issuance costs	(777,225)	—
Proceeds from exercise of stock options	1,655	—
Proceeds from exercise of pre-funded warrants	945	—
Net cash provided by (used in) financing activities	<u>33,115,222</u>	<u>(196,975)</u>
Net increase (decrease) in cash	27,208,242	(1,566,806)
Cash, beginning of period	1,928,474	4,308,821
Cash, end of period	<u>\$ 29,136,716</u>	<u>\$ 2,742,015</u>
Noncash investing and financing activities:		
Deferred offering costs included in accrued expenses	\$ 125,000	\$ 96,307
Conversion of convertible preferred stock to common stock upon initial public offering	\$ 45	\$ —
Private placement offering costs included in accounts payable	\$ 67,823	\$ —
Recognition of contingent warrant liability upon issuance of common stock in private placements	\$ 75,431	\$ —
Incremental fair value of preferred investment options exchanged in connection with August private placement	\$ 860,204	\$ —
Payment of accrued bonus through related party receivable	\$ 140,000	\$ —
Exercise of pre-funded warrants	\$ 6	\$ —

The accompanying notes are an integral part of these condensed financial statements.

BLUE WATER VACCINES INC.
Notes to Condensed Financial Statements
(Unaudited)

Note 1 — Organization and Basis of Presentation

Organization and Nature of Operations

Blue Water Vaccines Inc. (the “Company”) was formed on October 26, 2018, to focus on the research and development of transformational vaccines to prevent infectious diseases worldwide. The Company’s lead vaccine candidates, BWV-101 and BWV-102, are being investigated as a universal influenza vaccine with the potential to protect against all influenza strains and may provide a first-in-class long-term global vaccine that protects millions. The Company’s proprietary, immunogenic, multi-purpose platform enables the Company to bioengineer viral nanoparticles to deliver antigens, enhancing immunity, in an array of infectious disease agents, including influenza. All of the Company’s vaccine candidates are in the pre-clinical developmental stage.

Initial Public Offering

On February 23, 2022, the Company completed its initial public offering (“IPO”) in which the Company issued and sold 2,222,222 shares of its common stock, at a price to the public of \$9.00 per share. Proceeds from the IPO, net of underwriting discounts, commissions, and offering costs of \$2.9 million, were \$17.1 million. In connection with the completion of the IPO, all outstanding shares of convertible preferred stock were converted into 5,626,365 shares of common stock. See Note 6.

Stock Split

On November 24, 2021, the Company’s board of directors approved a 4-for-1 (4:1) stock split (the “Stock Split”) of the Company’s common stock without any change to its par value, which became effective on November 24, 2021. All references to share and per share amounts for all periods presented in these financial statements have been retrospectively restated to reflect the Stock Split and proportional adjustment of the preferred stock conversion ratio. Par values were not adjusted.

Basis of Presentation

The Company’s unaudited condensed financial statements have been prepared in conformity with accounting principles generally accepted in the United States of America (“U.S. GAAP”).

Note 2 — Liquidity and Financial Condition

The Company has had limited operating activities to date, substantially all of which have been devoted to seeking licenses and engaging in research and development activities. The Company’s product candidates currently under development will require significant additional research and development efforts prior to commercialization. The Company has financed its operations since inception primarily using proceeds received from seed investors, and proceeds received upon the completion of its IPO and private placements.

The Company has incurred substantial operating losses since inception and expects to continue to incur significant operating losses for the foreseeable future. As of September 30, 2022, the Company had cash of approximately \$29.1 million, working capital of approximately \$25.6 million and an accumulated deficit of approximately \$16.2 million.

On April 19, 2022, the Company completed a private placement in which it received approximately \$6.9 million in net cash proceeds, after deducting placement agent fees and other offering expenses, see Note 6. In addition, on August 11, 2022, the Company completed a private placement in which it received approximately \$8.7 million in net proceeds, after deducting placement agent fees and other offering expenses, see Note 6. The Company believes the existing cash at September 30, 2022, will be sufficient to continue operations, satisfy its obligations and fund the future expenditures that will be required to conduct the clinical and regulatory work to develop its product candidates for at least one year after the date that these financial statements are available to be issued. As such, the Company determined that it is not probable based on projected cash flows that substantial doubt about the Company’s ability to continue as a going concern exists for the one-year period following the date that the financial statements for the three and nine months ended September 30, 2022 were available to be issued.

The Company will require significant additional capital to make the investments it needs to execute its longer-term business plan. The Company expects a significant increase in cash outflows as compared to its historical spend for its planned pre-clinical development and clinical trial activities, and as such, it will need to raise additional capital to sustain operations and meet its long-term operating requirements beyond the one year period following the issuance of these financial statements. The Company expects to seek additional funding through additional debt or equity financings; however, there are currently no commitments in place for further financing nor is there any assurance that such financing will be available to the Company on favorable terms, if at all. If the Company is unable to secure additional capital, it may be required to curtail any clinical trials and development of products and take additional measures to reduce expenses in order to conserve its cash in amounts sufficient to sustain operations and meet its obligations in the long-term.

BLUE WATER VACCINES INC.
Notes to Condensed Financial Statements
(Unaudited)

Note 3 — Summary of Significant Accounting Policies

Use of Estimates

The preparation of financial statements in conformity with U.S. GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of expenses during the reporting periods. The most significant estimates in the Company's financial statements relate to the valuation of common stock, stock-based compensation, valuation of the contingent warrant liability, judgments used in the evaluation of potential loss contingencies, accrued research and development expenses and the valuation allowance of deferred tax assets resulting from net operating losses. These estimates and assumptions are based on current facts, historical experience and various other factors believed to be reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities and the recording of expenses that are not readily apparent from other sources. Actual results may differ materially and adversely from these estimates. To the extent there are material differences between the estimates and actual results, the Company's future results of operations will be affected.

Unaudited Interim Financial Statements

The accompanying condensed balance sheet as of September 30, 2022, the condensed statements of operations and the condensed statements of changes in stockholders' equity for the three and nine months ended September 30, 2022 and 2021, and the condensed statements of cash flows for the nine months ended September 30, 2022 and 2021 are unaudited. These unaudited interim financial statements have been prepared on the same basis as the audited financial statements, and in management's opinion, include all adjustments, consisting of only normal recurring adjustments, necessary for the fair statement of the Company's financial position as of September 30, 2022, the results of its operations for the three and nine months ended September 30, 2022 and 2021, and its cash flows for the nine months ended September 30, 2022 and 2021. The financial data and the other financial information disclosed in the notes to these condensed financial statements related to the three and nine-month periods are also unaudited. Operating results for the three and nine months ended September 30, 2022 are not necessarily indicative of the results that may be expected for the year ending December 31, 2022, any other interim periods, or any future year or period. The unaudited condensed financial statements included in this Quarterly Report on Form 10-Q should be read in conjunction with the audited financial statements and notes thereto included in the Company's annual report on Form 10-K for the year ended December 31, 2021, which includes a broader discussion of the Company's business and the risks inherent therein.

Concentration of Credit Risk

Financial instruments that potentially subject the Company to concentrations of credit risk consist of cash accounts in a financial institution, which, at times, may exceed the Federal Depository Insurance Coverage limit of \$250,000. As of September 30, 2022 and December 31, 2021, the Company has not experienced losses on these accounts and management believes the Company is not exposed to significant risks on such accounts.

Property and Equipment

Property and equipment consists of computers and office furniture and fixtures, all of which are recorded at cost. Depreciation is recorded using the straight-line method over the respective useful lives of the assets ranging from three to seven years. Long-lived assets are reviewed for impairment whenever events or circumstances indicate that the carrying amount of these assets may not be recoverable.

Fair Value Measurements

Fair value is defined as the price that would be received for sale of an asset or paid for transfer of a liability, in an orderly transaction between market participants at the measurement date. U.S. GAAP establishes a three-tier fair value hierarchy, which prioritizes the inputs used in measuring fair value. The hierarchy gives the highest priority to unadjusted quoted prices in active markets for identical assets or liabilities (Level 1 measurements) and the lowest priority to unobservable inputs (Level 3 measurements). These tiers include:

- Level 1, defined as observable inputs such as quoted prices (unadjusted) for identical instruments in active markets;

BLUE WATER VACCINES INC.
Notes to Financial Statements

Note 3 — Summary of Significant Accounting Policies (cont.)

- Level 2, defined as inputs other than quoted prices in active markets that are either directly or indirectly observable such as quoted prices for similar instruments in active markets or quoted prices for identical or similar instruments in markets that are not active; and
- Level 3, defined as unobservable inputs in which little or no market data exists, therefore requiring an entity to develop its own assumptions, such as valuations derived from valuation techniques in which one or more significant inputs or significant value drivers are unobservable.

In some circumstances, the inputs used to measure fair value might be categorized within different levels of the fair value hierarchy. In those instances, the fair value measurement is categorized in its entirety in the fair value hierarchy based on the lowest level input that is significant to the fair value measurement. Financial instruments, including cash, prepaid expenses, deferred offering costs, receivables from related party, accounts payable and accrued liabilities are carried at cost, which management believes approximates fair value due to the short-term nature of these instruments. As of December 31, 2021, none of the Company's non-financial assets or liabilities were recorded at fair value on a non-recurring basis. No transfers between levels have occurred during the periods presented. The contingent warrant liability that became issuable upon the closing of the private placements during the nine months ended September 30, 2022, are valued on a recurring basis utilizing a Monte Carlo simulation which includes Level 3 inputs. See Note 6. The following assumptions were used for the valuation of the contingent warrant liability upon the various commitment dates:

	April 19, 2022	August 11, 2022
Exercise price	\$ 8,46875	\$ 3,3938
Term (years)	4.00	5.00
Expected stock price volatility	117.0%	127.82%
Risk-free rate of interest	2.86%	2.98%

The fair value of financial instruments measured on a recurring basis is as follows:

Description	As of September 30, 2022			
	Total	Level 1	Level 2	Level 3
Liabilities:				
Contingent warrant liability	\$ 42,056	—	—	\$ 42,056

The following table summarizes the change in fair value, as determined by Level 3 inputs, for the contingent warrant liability using unobservable Level 3 inputs for the nine months ended September 30, 2022:

	Contingent Warrant Liability
Balance at December 31, 2021	\$ —
Fair value at issuance	75,431
Change in fair value	(33,375)
Balance at September 30, 2022	\$ 42,056

Deferred Offering Costs

The Company capitalizes certain legal, professional accounting and other third-party fees that are directly associated with in-process equity financings as deferred offering costs until such financings are consummated. After consummation of the equity financing, these costs are recorded in stockholders' equity as a reduction of proceeds generated as a result of the offering. Should the in-process equity financing be abandoned, the deferred offering costs will be expensed immediately as a charge to operating expenses in the statements of operations. As of September 30, 2022, all previously deferred offering costs related to the IPO, totaling approximately \$0.8 million, and of which \$0.3 million were paid during 2021, were netted against the proceeds received upon the closing of the IPO, which occurred on February 23, 2022.

Research and Development

The Company expenses the cost of research and development as incurred. Research and development expenses include costs incurred in funding research and development activities, license fees, and other external costs. Advance payments for goods and services that will be used in future research and development activities are expensed when the activity has been performed or when the goods have been received rather than when the payment is made. Upfront and milestone payments due to third parties that perform research and development services on the Company's behalf will be expensed as services are rendered or when the milestone is achieved. When billing terms under research and development contracts do not coincide with the timing of when the work is performed, the Company is required to make estimates of outstanding obligations as of period end to those third parties. Accrual estimates are based on several factors, including the Company's knowledge of the progress towards completion of the research and development activities, invoicing to date under the contracts, communication from the research institution or other companies of any actual costs incurred during the period that have not yet been invoiced, and the costs included in the contracts. Significant judgments and estimates may be made in determining the accrued balances at the end of any reporting period. Actual results could differ from the estimates made by the Company. The historical accrual estimates made by the Company have not been materially different from the actual costs. See Notes 5 and 7.

BLUE WATER VACCINES INC.
Notes to Financial Statements

Note 3 — Summary of Significant Accounting Policies (cont.)

In accordance with FASB ASC Topic 730-10-25-1, *Research and Development*, costs incurred in obtaining licenses and patent rights are charged to research and development expense if the technology licensed has not reached commercial feasibility and has no alternative future use. The licenses purchased by the Company (see Note 5) require substantial completion of research and development, regulatory and marketing approval efforts to reach commercial feasibility and have no alternative future use. Accordingly, the total purchase price for the licenses acquired is reflected as research and development on the Company's statements of operations.

Contingencies

Accruals are recorded for loss contingencies when it is probable that a liability has been incurred and the amount of the related loss can be reasonably estimated. The Company evaluates, on a quarterly basis, developments in legal proceedings and other matters that could cause an increase or decrease in the amount of the liability that has been accrued previously. Considering facts known at the time of the assessment, the Company determines whether potential losses are considered reasonably possible or probable and whether they are estimable. Based upon this assessment, the Company carries out an evaluation of disclosure requirements and considers possible accruals in the financial statements.

Stock-Based Compensation

The Company expenses stock-based compensation to employees and non-employees over the requisite service period based on the estimated grant-date fair value of the awards. Stock-based awards to employees with graded-vesting schedules are recognized using the accelerated attribution method, on a straight-line basis over the requisite service period for each separately vesting portion of the award.

The Company estimates the fair value of stock option grants using the Black-Scholes option pricing model and the assumptions used in calculating the fair value of stock-based awards represent management's best estimates and involve inherent uncertainties and the application of management's judgment.

Expected Term — The expected term of options represents the period that the Company's stock-based awards are expected to be outstanding based on the simplified method, which is the half-life from vesting to the end of its contractual term.

Expected Volatility — Volatility is a measure of the amount by which the Company's share price has historically fluctuated or is expected to fluctuate (i.e., expected volatility) during a period. Due to the lack of an adequate history of a public market for the trading of the Company's common stock and a lack of adequate company-specific historical and implied volatility data, the Company computes stock price volatility over expected terms based on comparable companies' historical common stock trading prices. For these analyses, the Company has selected companies with comparable characteristics, including enterprise value, risk profiles, and position within the industry.

Common Stock Fair Value — Due to the absence of an active market for the Company's common stock prior to the IPO, the fair value of the common stock underlying the Company's stock options granted prior to the IPO was estimated at each grant date and was determined with the assistance of an independent third-party valuation expert. The assumptions underlying these valuations represented management's best estimates, which involved inherent uncertainties and the application of significant levels of management judgment. After the completion of the IPO, the fair value of each share of common stock is based on the closing price of the Company's common stock as reported by the Nasdaq Capital Market.

Risk-Free Interest Rate — The Company bases the risk-free interest rate on the implied yield available on U.S. Treasury securities with a remaining term commensurate with the estimated expected term.

Expected Dividend — The Company has never declared or paid any cash dividends on its shares of common stock and does not plan to pay cash dividends in the foreseeable future, and, therefore, uses an expected dividend yield of zero in its valuation models.

The Company recognizes forfeitures of equity awards as they occur.

Fair Value of Common Stock

In order to determine the fair value of shares of common stock of the Company when issuing stock options prior to the IPO, its board of directors considered with input from third party valuations, among other things, contemporaneous valuations of the Company's common stock. Given the absence of a public trading market of the Company's capital stock prior to its IPO, its board of directors has exercised reasonable judgment and considered a number of objective and subjective factors to determine the best estimate of the fair value of the Company common and preferred stock, including:

- the prices, rights, preferences and privileges of the Company's preferred stock relative to the Company's common stock;
- the Company's business, financial condition and results of operations, including related industry trends affecting the Company's operations;

BLUE WATER VACCINES INC.
Notes to Financial Statements

Note 3 — Summary of Significant Accounting Policies (cont.)

- the likelihood of achieving a liquidity event, such as an IPO, or sale of the Company, given prevailing market conditions;
- the lack of marketability of the Company's common stock;
- the market performance of comparable publicly traded companies;
- U.S. and global economic and capital market conditions and outlook; and
- common stock valuation methodology.

In estimating the fair market value of common stock of the Company, its board of directors first determined the equity value of its business using accepted valuation methods.

The Company engaged a third-party valuation specialist to conduct a valuation, which used its most recent preferred stock financing as a starting point and determined the equity value of the Company based on the Backsolve method using an Option Pricing Method (OPM) to calculate the implied value based on a market approach. The Company's equity value was allocated using OPM to estimate the fair market value of the Company's classes of equity.

After the completion of the IPO, the fair value of each share of common stock is based on the closing price of the Company's common stock as reported by the Nasdaq Capital Market.

Income Taxes

Income taxes are accounted for under the asset and liability method. Deferred tax assets and liabilities are recognized for future tax consequences attributable to differences between the financial statement carrying amounts of existing assets and liabilities and their respective tax bases and operating loss and tax credit carryforwards.

Deferred tax assets and liabilities are measured using enacted tax rates expected to apply to taxable income in the years in which those temporary differences are expected to be recovered or settled. The effect on deferred tax assets and liabilities of a change in tax rate is recognized in operations in the period that includes the enactment date. Deferred tax assets are reduced to estimated amounts expected to be realized by the use of a valuation allowance.

Comprehensive Income (Loss)

The Company is required to report all components of comprehensive income (loss), including net income (loss), in the accompanying condensed financial statements in the period in which they are recognized. Comprehensive income (loss) is defined as the change in equity during a period from transactions and other events and circumstances from non-owner sources, including unrealized gains and losses on investments and foreign currency translation adjustments. Net loss and comprehensive loss were the same for all periods presented.

Warrants

The Company determines the accounting classification of warrants that are issued, as either liability or equity, by first assessing whether the warrants meet liability classification in accordance with ASC 480-10, *Accounting for Certain Financial Instruments with Characteristics of both Liabilities and Equity*, ("ASC 480-10"), and then in accordance with ASC 815-40, *Derivatives and Hedging - Contracts in Entity's Own Equity* ("ASC 815-40"). Under ASC 480-10, warrants are considered liability-classified if the warrants are mandatorily redeemable, obligate the issuer to settle the warrants or the underlying shares by paying cash or other assets, or must or may require settlement by issuing variable number of shares.

If the warrants do not meet liability classification under ASC 480-10, the Company assesses the requirements under ASC 815-40, which states that contracts that require or may require the issuer to settle the contract for cash are liabilities recorded at fair value, irrespective of the likelihood of the transaction occurring that triggers the net cash settlement feature. If the warrants do not require liability classification under ASC 815-40, in order to conclude equity classification, the Company assesses whether the warrants are indexed to its common stock and whether the warrants are classified as equity under ASC 815-40 or other applicable GAAP. After all relevant assessments are made, the Company concludes whether the warrants are classified as liability or equity. Liability-classified warrants are required to be accounted for at fair value both on the date of issuance and on subsequent accounting period ending dates, with all changes in fair value after the issuance date recorded as a component of other income (expense), net in the statements of operations. Equity-classified warrants are accounted for at fair value on the issuance date with no changes in fair value recognized after the issuance date. As of September 30, 2022, all of the Company's outstanding warrants are equity-classified warrants, except for the contingent warrants that became issuable upon the close of the April and August private placements. See Note 6.

BLUE WATER VACCINES INC.
Notes to Financial Statements

Note 3 — Summary of Significant Accounting Policies (cont.)

Net Loss Per Share

Basic loss per share is computed by dividing the net income or loss applicable to common shares by the weighted average number of common shares outstanding during the period, including pre-funded warrants because their exercise requires only nominal consideration for the delivery of shares. Diluted earnings per share is computed using the weighted average number of common shares and, if dilutive, potential common shares outstanding during the period. Potential common shares consist of the Company's preferred stock, warrants and options. Diluted loss per share excludes the shares issuable upon the conversion of preferred stock, as well as common stock options and warrants, from the calculation of net loss per share if their effect would be anti-dilutive.

The two-class method is used to determine earnings per share based on participation rights of participating securities in any undistributed earnings. Each preferred stock that includes rights to participate in distributed earnings is considered a participating security and the Company uses the two-class method to calculate net income available to the Company's common stockholders per common share — basic and diluted.

The following securities were excluded from the computation of diluted shares outstanding due to the losses incurred in the periods presented, as they would have had an anti-dilutive impact on the Company's net loss:

	Three Months Ended		Nine Months Ended	
	September 30,		September 30,	
	2022	2021	2022	2021
Options to purchase shares of common stock	1,383,801	780,640	1,383,801	780,640
Series Seed Preferred Stock	—	4,584,552	—	4,584,552
Warrants issued upon close of IPO	111,111	—	111,111	—
Private Placement Warrants	5,264,274	—	5,264,274	—
Total	6,759,186	5,365,192	6,759,186	5,365,192

New Accounting Pronouncements

In April 2012, the Jump-Start Our Business Startups Act (the "JOBS Act") was signed into law. The JOBS Act contains provisions that, among other things, reduce certain reporting requirements for an emerging growth company. As an emerging growth company, the Company may elect to adopt new or revised accounting standards when they become effective for non-public companies, which typically is later than when public companies must adopt the standards. The Company has elected to take advantage of the extended transition period afforded by the JOBS Act and, as a result, unless the Company elects early adoption of any standards, will adopt the new or revised accounting standards on the relevant dates on which adoption of such standards is required for non-public companies.

In August 2020, the FASB issued Accounting Standard Update ("ASU") No. 2020-06, *Debt — Debt with Conversion and Other Options (Subtopic 470-20) and Derivatives and Hedging — Contracts in Entity's Own Equity (Subtopic 815-40): Accounting for Convertible Instruments and Contracts in an Entity's Own Equity*, which simplifies accounting for convertible instruments by removing major separation models required under current GAAP. The ASU also removes certain settlement conditions that are required for equity contracts to qualify for the derivative scope exception and it also simplifies the diluted earnings per share calculation in certain areas. This guidance is effective for public business entities except for smaller reporting companies for fiscal years, and interim periods within those fiscal years, beginning after December 15, 2021. For all other entities, the standard will be effective for fiscal years beginning after December 15, 2023, including interim periods within those fiscal years. Early adoption is permitted. The Company adopted ASU 2020-06 on January 1, 2022, using the modified retrospective method, and the adoption of the ASU did not impact the Company's financial position, results of operations, cash flows or net loss per share.

BLUE WATER VACCINES INC.
Notes to Financial Statements

Note 3 — Summary of Significant Accounting Policies (cont.)

In October 2020, the FASB issued ASU 2020-10, *Codification Improvements*, which updates various codification topics by clarifying or improving disclosure requirements to align with the SEC’s regulations. The Company adopted ASU 2020-10 as of the reporting period beginning January 1, 2022. The adoption of this update did not have a material effect on the Company’s financial statements.

In May 2021, the FASB issued ASU 2021-04, *Earnings Per Share (Topic 260), Debt — Modifications and Extinguishments (Subtopic 470-50), Compensation — Stock Compensation (Topic 718), and Derivatives and Hedging — Contracts in Entity’s Own Equity (Subtopic 815-40): Issuer’s Accounting for Certain Modifications or Exchanges of Freestanding Equity-Classified Written Call Options (a consensus of the FASB Emerging Issues Task Force)*. The ASU clarifies and reduces diversity in an issuer’s accounting for modifications or exchanges of freestanding equity-classified written call options (for example, warrants) that remain equity classified after modification or exchange. The ASU provides guidance that will clarify whether an issuer should account for a modification or an exchange of a freestanding equity-classified written call option that remains equity classified after modification or exchange as (1) an adjustment to equity and, if so, the related earnings per share (EPS) effects, if any, or (2) an expense and, if so, the manner and pattern of recognition. The new guidance is effective for all entities for annual and interim periods beginning after December 15, 2021, and early adoption is permitted, including adoption in an interim period. The Company adopted ASU 2021-04 on January 1, 2022, and the adoption of the ASU did not impact the Company’s financial position, results of operations, cash flows, or net loss per share.

In June 2022, the FASB issued ASU No. 2022-03, *Fair Value Measurement (Topic 820): Fair Value Measurement of Equity Securities Subject to Contractual Sale Restrictions* (“ASU 2022-03”), which applies to all equity securities measured at fair value that are subject to contractual sale restrictions. This change prohibits entities from taking into account contractual restrictions on the sale of equity securities when estimating fair value and introduces required disclosures for such transactions. This guidance is effective for public business entities beginning after December 15, 2023, including interim periods within those fiscal years. For all other entities, the standard will be effective for fiscal years beginning after December 15, 2024, including interim periods within those fiscal years. Early adoption is permitted. The Company adopted ASU 2022-03 effective July 1, 2022, and the adoption of the ASU did not impact the Company’s financial position, results of operations, cash flows, or net loss per share.

The Company’s management does not believe that any other recently issued, but not yet effective, accounting standards if currently adopted would have a material effect on the accompanying condensed financial statements.

Note 4 — Balance Sheet Details

Prepaid Expenses

Prepaid expenses consisted of the following as of September 30, 2022 and December 31, 2021:

	As of September 30, 2022	As of December 31, 2021
Prepaid research and development	\$ 125,281	\$ 203,910
Prepaid insurance	434,762	4,842
Prepaid other	143,786	25,799
Total	\$ 703,829	\$ 234,551

BLUE WATER VACCINES INC.
Notes to Financial Statements

Note 4 — Balance Sheet Details (cont.)

Accrued Expenses

Accrued expenses consisted of the following as of September 30, 2022 and December 31, 2021:

	As of September 30, 2022	As of December 31, 2021
Accrued license fees	\$ 12,500	\$ 225,000
Accrued research and development	994,875	300,182
Accrued deferred offering costs	125,000	246,236
Accrued compensation	815,902	234,265
Accrued loss contingency	1,313,924	—
Accrued director fees	86,875	—
Accrued other	205,937	49,832
Total	\$ 3,555,013	\$ 1,055,515

Note 5 — Significant Agreements

Oxford University Innovation Limited

In December 2018, the Company entered into an option agreement with Oxford University Innovation (“OUI”), which was a precursor to a license agreement (the “OUI Agreement”), dated July 16, 2019. Under the terms of the OUI Agreement, the Company holds an exclusive, worldwide license to certain specified patent rights and biological materials relating to the use of epitopes of limited variability and virus-like particle products and practice processes that are covered by the licensed patent rights and biological materials for the purpose of developing and commercializing a vaccine product candidate for influenza. The Company is obligated to use its best efforts to develop and market Licensed Products, as defined in the OUI Agreement, in accordance with its development plan, report to OUI on progress, achieve the following milestones and must pay OUI nonrefundable milestone fees when it achieves them: initiation of first Phase I study; initiation of first Phase II study; initiation of first Phase III/pivotal registration studies; first submission of application for regulatory approval (BLA/NDA); marketing authorization in the United States; marketing authorization in any EU country; marketing authorization in Japan; first marketing authorization in any other country; first commercial sale in Japan; first commercial sale in any ROW country; first year that annual sales equal or exceed certain thresholds. See Note 7 for additional information on the milestone payments as well as royalty obligations required under the OUI Agreement. The OUI Agreement will expire upon ten (10) years from the expiration of the last patent contained in the licensed patent rights, unless terminated earlier. During the year ended December 31, 2021, the U.S. Patent related to immunogenic composition was issued to OUI. This patent expires in August 2037. No additional patents have been issued during the three and nine months ended September 30, 2022. Either party may terminate the OUI Agreement for an uncured material breach. The Company was able to terminate the OUI Agreement for any reason at any time upon six months’ written notice until July 16, 2022, which was the third anniversary of the OUI Agreement. OUI may terminate immediately if the Company has a petition presented for its winding-up or passes a resolution for winding up other than for a bona fide amalgamation or reconstruction or compounds with its creditors or has a receiver or administrator appointed. OUI may also terminate if the Company opposes or challenges the validity of any of the patents or applications in the Licensed Technology, as defined in the OUI Agreement; raises the claim that the know-how of the Licensed Technology is not necessary to develop and market Licensed Products; or in OUI’s reasonable opinion, is taking inadequate or insufficient steps to develop or market Licensed Products and does not take any further steps that OUI requests by written notice within a reasonable time.

For the three and nine months ended September 30, 2022 and 2021, the Company did not incur any licensing fee payments for intellectual property licenses.

See Note 7.

BLUE WATER VACCINES INC.
Notes to Financial Statements

Note 5 — Significant Agreements (cont.)

St. Jude Children's Hospital

The Company entered into a license agreement (the "St. Jude Agreement"), dated January 27, 2020, with St. Jude Children's Research Hospital ("St. Jude"). Under the terms of the St. Jude Agreement, the Company holds an exclusive, worldwide license to certain specified patent rights and biological materials relating to the use of live attenuated streptococcus pneumoniae and practice processes that are covered by the licensed patent rights and biological materials for the purpose of developing and commercializing a vaccine product candidate for streptococcus pneumoniae. The St. Jude Agreement will expire upon the expiration of the last valid claim contained in the licensed patent rights, unless terminated earlier. The Company is obligated to use commercially reasonable efforts to develop and commercialize the licensed product(s). The milestones include the following events: (i) complete IND enabling study; (ii) initiate animal toxicology study; (iii) file IND; (iv) complete Phase I Clinical Trial; (v) commence Phase II Clinical Trial; (vi) commence Phase III Clinical Trial; and, (vii) regulatory approval, U.S. or foreign equivalent. If the Company fails to achieve the development milestones contained in the St. Jude Agreement, and if the Company and St. Jude fail to agree upon a mutually satisfactory revised timeline, St. Jude will have the right to terminate the St. Jude Agreement. Either party may terminate the St. Jude Agreement in the event the other party (a) files or has filed against it a petition under the Bankruptcy Act (among other things) or (b) fails to perform or otherwise breaches its obligations under the St. Jude Agreement, and has not cured such failure or breach within sixty (60) days. The Company may terminate for any reason on thirty (30) days written notice. On May 11, 2022, the Company entered into an amendment to the St. Jude Agreement, whereby the royalty terms, milestone payments and licensing fees were amended, and a revised development milestone timeline was agreed to. See Note 7 for more information on this amendment.

For the three and nine months ended September 30, 2022, the Company recognized approximately \$3,000 and \$13,000, respectively, for intellectual property licenses, which is recorded as research and development expenses. For the three and nine months ended September 30, 2021, the Company recognized \$0 and \$10,000 for intellectual property licenses, respectively, which is recorded as research and development expenses. See Note 7 for additional information on the milestone payments as well as royalty obligations required under the St. Jude Agreement.

Cincinnati Children's Hospital Medical Center

The Company entered into a license agreement (the "CHMC Agreement"), dated June 1, 2021, with Children's Hospital Medical Center, d/b/a Cincinnati Children's Hospital Medical Center ("CHMC"). Under the terms of the CHMC Agreement, the Company holds an exclusive, worldwide license (other than the excluded field of immunization against, and prevention, control, or reduction in the severity of gastroenteritis caused by rotavirus and norovirus in China and Hong Kong) to certain specified patent and biological materials relating to the use of norovirus nanoparticles and practice processes that are covered by the licensed patent rights and biological materials for the purpose of developing and commercializing CHMC patents and related technology directed to a virus-like particle vaccine platform that utilizes nanoparticle delivery technology that may have potential broad application to develop vaccines for multiple infectious diseases. The term of the CHMC Agreement begins on the effective date and extends on a jurisdiction by jurisdiction and product by product basis until the later of: (i) the last to expire licensed patent; (ii) ten (10) years after the first commercial sale; or, (iii) entrance onto the market of a biosimilar or interchangeable product. The Company is obligated to use commercially reasonable efforts to bring licensed products to market through diligent research and development, testing, manufacturing and commercialization, to use best efforts to make all necessary regulatory filings and obtain all necessary regulatory approvals, to achieve milestones relating to development and sales, and report to CHMC on progress. The Company will also be obligated to pay the agreed upon development milestone payments to CHMC, as well as royalty payments, see Note 7 for additional information. The Company may terminate the CHMC Agreement for convenience, at any time prior to first commercial sale of a product or process by providing one hundred and eighty (180) days' written notice to CHMC. It may also terminate for a CHMC uncured material breach. CHMC may terminate the CHMC Agreement for an uncured Company material breach or insolvency or bankruptcy. Pursuant to the terms of the CHMC Agreement, if the Company fails to achieve the milestones, and cannot mutually agree with CHMC on an amendment to the milestones, then CHMC will have the option of converting any and all of such exclusive licenses to nonexclusive licenses, to continue developing indications that have already entered development at any stage or in which the Company has invested in developing. CHMC may also terminate the CHMC Agreement to the fullest extent permitted by law in the countries of the worldwide territory, in the event the Company or its affiliates challenge or induce others set up challenges to the validity or enforceability of any of the Licensed Patents, as defined in the CHMC Agreement, and the Company will be obligated to reimburse CHMC for its costs, including reasonable attorneys' fees.

BLUE WATER VACCINES INC.
Notes to Financial Statements

Note 5 — Significant Agreements (cont.)

For the three and nine months ended September 30, 2022, the Company did not incur any licensing fee payments for intellectual property licenses. For the three and nine months ended September 30, 2021, the Company accrued licensing fee payments for intellectual property licenses, which is recorded as research and development expenses, in aggregate of approximately \$25,000 and \$402,000, respectively. See Note 7.

Ology Bioservices, Inc. (which was later acquired by National Resilience, Inc.)

The Company entered into a Master Services Agreement (“Ology MSA”), dated July 19, 2019, with Ology, Inc. (“Ology”) to provide services from time to time, including but not limited to technology transfer, process development, analytical method optimization, cGMP manufacture, regulatory affairs, and stability studies of biologic products. Pursuant to the Ology MSA, the Company and Ology shall enter into a Project Addendum for each project to be governed by the terms and conditions of the Ology MSA.

The Company has entered into two Project Addendums as of September 30, 2022 and December 31, 2021. The initial Project Addendum was executed on October 18, 2019 and the Company was required to pay Ology an aggregate of approximately \$4 million. Due to unforeseen delays associated with COVID-19, the Company and Ology entered into a letter agreement dated January 9, 2020 to stop work on the project. The Company paid Ology \$100,000 for services, of which \$48,600 remained as a prepaid expense as of December 31, 2020. The second Project Addendum was executed on May 21, 2021 and the Company is obligated to pay Ology an aggregate amount of approximately \$2.8 million, plus reimbursement for materials and outsourced testing, which will be billed at cost plus 15%. This project began during 2021, and the Company recorded approximately \$164,000 and \$115,000 as related accounts payable and accrued expenses, respectively, at December 31, 2021. On April 20, 2022, the Company entered into an amendment to the Ology MSA, whereby the Company’s obligations increased by \$300,000, specifically related to regulatory support on the project. On August 30, 2022, the Company entered into another amendment to the Ology MSA which reduced the Company’s obligations by approximately \$379,000 as a result of changes in the scope of work related to certain tasks defined in the second Project Addendum. During the three and nine months ended September 30, 2022, the Company incurred related research and development expenses of approximately \$496,000 and \$988,000, respectively, and had approximately \$53,000 and \$851,000 recorded as related accounts payable and accrued expenses, respectively, at September 30, 2022. There was approximately \$71,000 of related expenses incurred during the three and nine months ended September 30, 2021.

Note 6 — Stockholders’ Equity

Authorized Capital and Stock Split

On February 23, 2022, the Company filed with the Secretary of State of the State of Delaware an amended and restated certificate of incorporation (the “A&R COI”), which became effective immediately. The Company’s board of directors and stockholders approved the A&R COI to be effective upon the closing of the IPO. There was no change to the Company’s authorized shares of common stock and preferred stock of 250,000,000 shares and 10,000,000 shares, respectively, or the par value, which is \$0.00001 for both common and preferred stock. Prior to this amendment, the Company had designated 1,150,000 shares of preferred stock, with par value \$0.00001 per share. In addition, on February 23, 2022 and in connection with the closing of the IPO, the Company’s board of directors adopted Amended and Restated Bylaws.

Common Stock

As of September 30, 2022 and December 31, 2021, there were 14,689,851 and 3,200,000 shares of common stock issued and outstanding, respectively.

Holders of the Company’s common stock are entitled to one vote for each share held of record, and are entitled upon liquidation of the Company to share ratably in the net assets of the Company available for distribution after payment of all obligations of the Company and after provision has been made with respect to each class of stock, if any, having preference over the common stock, currently including the Company’s preferred stock. The shares of common stock are not redeemable and have no preemptive or similar rights.

On February 17, 2022, the Company entered into an underwriting agreement (the “Underwriting Agreement”) with Boustead Securities, LLC, acting as representative of the underwriters (“Boustead”), in relation to the Company’s IPO, pursuant to which the Company agreed to sell to the underwriters an aggregate of 2,222,222 shares of the Company’s common stock, at a price of \$9.00 per share. The IPO closed on February 23, 2022, and resulted in net proceeds to the Company, after deducting the 8% underwriting discount, and other offering costs, of approximately \$17.1 million. Pursuant to the Underwriting Agreement, the Company issued to Boustead warrants to purchase 111,111 shares of common stock. As of September 30, 2022, the warrants were exercisable, at the option of the holder, at a per share exercise price equal to \$10.35, and were exercisable at any time and from time to time, in whole or in part, starting on February 23, 2022 and terminating on February 11, 2027. Subsequent to September 30, 2022, the warrants were exchanged for 93,466 shares of restricted stock. See Notes 7 and 11.

The Company evaluated the terms of the warrants issued at the close of the IPO and determined that they should be classified as equity instruments based upon accounting guidance provided in ASC 480 and ASC 815-40. Since the Company determined that the warrants were equity-classified, the Company recorded the proceeds from the IPO, net of issuance costs, within common stock at par value and the balance of the net proceeds to additional paid in capital.

BLUE WATER VACCINES INC.
Notes to Financial Statements

Note 6 — Stockholders' Equity (cont.)

Private Investments in Public Equity

April Private Placement

On April 19, 2022, the Company consummated the closing of a private placement (the "April Private Placement"), pursuant to the terms and conditions of a securities purchase agreement, dated as of April 13, 2022. At the closing of the April Private Placement, the Company issued 590,406 shares of common stock, pre-funded warrants to purchase an aggregate of 590,406 shares of common stock and preferred investment options to purchase up to an aggregate of 1,180,812 shares of common stock. The purchase price of each share of common stock together with the associated preferred investment option was \$6.775, and the purchase price of each pre-funded warrant together with the associated preferred investment option was \$6.774. The aggregate net cash proceeds to the Company from the April Private Placement were approximately \$6.9 million, after deducting placement agent fees and other offering expenses. The pre-funded warrants had an exercise price of \$0.001 per share, were exercisable on or after April 19, 2022, and were exercisable until the pre-funded warrants were exercised in full. The pre-funded warrants were exercised in full on May 24, 2022, and as such the Company issued 590,406 shares of common stock on that date. The preferred investment options were exercisable at any time on or after April 19, 2022 through April 20, 2026, at an exercise price of \$6.65 per share, subject to certain adjustments as defined in the agreement.

H.C. Wainwright & Co., LLC ("Wainwright") acted as the exclusive placement agent for the April Private Placement. The Company agreed to pay Wainwright a placement agent fee and management fee equal to 7.5% and 1.0%, respectively, of the aggregate gross proceeds from the April Private Placement and reimburse certain out-of-pocket expenses up to an aggregate of \$85,000. In addition, the Company issued warrants to Wainwright (the "April Wainwright Warrants") to purchase up to 70,849 shares of common stock. The Wainwright Warrants are in substantially the same form as the preferred investment options, except that the exercise price is \$8.46875. The form of the preferred investment options is a warrant, and as such the preferred investment options, the pre-funded warrants, and the Wainwright Warrants are collectively referred to as the "April Private Placement Warrants". Further, upon any exercise for cash of any preferred investment options, the Company agreed to issue to Wainwright additional warrants to purchase the number of shares of common stock equal to 6.0% of the aggregate number of shares of common stock underlying the preferred investment options that have been exercised, also with an exercise price of \$8.46875 (the "April Contingent Warrants"). The maximum number of April Contingent Warrants issuable under this provision is 70,849.

In connection with the April Private Placement, the Company entered into a Registration Rights Agreement with the purchasers, dated as of April 13, 2022 (the "April Registration Rights Agreement"). The April Registration Rights Agreement provides that the Company shall file a registration statement covering the resale of all of the registrable securities (as defined in the April Registration Rights Agreement) with the Securities and Exchange Commission (the "SEC") no later than the 20th calendar day following the date of the April Registration Rights Agreement and have the registration statement declared effective by the SEC as promptly as possible after the filing thereof, but in any event no later than the 45th calendar day following April 13, 2022 or, in the event of a full review by the SEC, the 75th day following April 13, 2022. The registration statement on Form S-1 required under the Registration Rights Agreement was filed with the SEC on May 3, 2022, and became effective on May 20, 2022.

Upon the occurrence of any Event (as defined in the April Registration Rights Agreement), which, among others, prohibits the purchasers from reselling the securities for more than ten consecutive calendar days or more than an aggregate of fifteen calendar days during any 12-month period, and should the registration statement cease to remain continuously effective, the Company is obligated to pay to each purchaser, on each monthly anniversary of each such Event, an amount in cash, as partial liquidated damages and not as a penalty, equal to the product of 2.0% multiplied by the aggregate subscription amount paid by such purchaser in the April Private Placement. As of September 30, 2022, the Company determined that the likelihood of the Company incurring liquidated damages pursuant to the April Registration Rights Agreement is remote, and as such no accrual of these payments is required as of September 30, 2022.

The Company evaluated the terms of the April Private Placement Warrants and determined that they should be classified as equity instruments based upon accounting guidance provided in ASC 480 and ASC 815-40. Since the Company determined that the April Private Placement Warrants were equity-classified, the Company recorded the proceeds from the April Private Placement, net of issuance costs, within common stock at par value and the balance of the net proceeds to additional paid in capital.

The Company evaluated the terms of the April Contingent Warrants and determined that they should be classified as a liability based upon accounting guidance provided in ASC 815-40. Since the April Contingent Warrants are a form of compensation to the placement agent, the Company recorded the value of the liability of approximately \$36,000, as a reduction of additional paid in capital, with subsequent changes in the value of the liability recorded in other income (expense) in the accompanying condensed statements of operations. The Company measured the liability upon the close of the April Private Placement using a Monte Carlo simulation. See Note 3.

On August 11, 2022, the investors in the April Private Placement agreed to cancel the aggregate of 1,180,812 preferred investment options issued in the April Private Placement, as part of their participation in the August Private Placement. Concurrent with the cancellation of the April preferred investment options, which was accounted for as an exchange of equity-linked financial instruments, the April Contingent Warrants, which are issuable only upon exercise of the preferred investment options, were also modified. See 'August Private Placement' below for further detail.

BLUE WATER VACCINES INC.
Notes to Financial Statements

Note 6 — Stockholders' Equity (cont.)

August Private Placement

On August 11, 2022, the Company consummated the closing of a private placement (the "August Private Placement"), pursuant to the terms and conditions of a securities purchase agreement, dated as of August 9, 2022. At the closing of the August Private Placement, the Company issued 1,350,000 shares of common stock, pre-funded warrants to purchase an aggregate of 2,333,280 shares of common stock and preferred investment options to purchase up to an aggregate of 4,972,428 shares of common stock. The purchase price of each share of common stock together with the associated preferred investment option was \$2.715, and the purchase price of each pre-funded warrant together with the associated preferred investment option was \$2.714. The aggregate net cash proceeds to the Company from the August Private Placement were approximately \$8.7 million, after deducting placement agent fees and other offering expenses. In addition, the investors in the August Private Placement, who are the same investors from the April Private Placement, agreed to cancel preferred investment options to purchase up to an aggregate of 1,180,812 shares of the Company's common stock issued in April 2022. The pre-funded warrants have an exercise price of \$0.001 per share, are exercisable on or after August 11, 2022, and are exercisable until the pre-funded warrants are exercised in full. On September 20, 2022, 945,000 of the pre-funded warrants were exercised, and as such the Company issued 945,000 shares of common stock on that date. The preferred investment options are exercisable at any time on or after August 11, 2022 through August 12, 2027, at an exercise price of \$2.546 per share, subject to certain adjustments as defined in the agreement.

Wainwright acted as the exclusive placement agent for the August Private Placement. The Company agreed to pay Wainwright a placement agent fee and management fee equal to 7.5% and 1.0%, respectively, of the aggregate gross proceeds from the August Private Placement and reimburse certain out-of-pocket expenses up to an aggregate of \$85,000. In addition, the Company issued warrants to Wainwright (the "August Wainwright Warrants") to purchase up to 220,997 shares of common stock. The August Wainwright Warrants are in substantially the same form as the preferred investment options, except that the exercise price is \$3.3938. The form of the preferred investment options is a warrant, and as such the preferred investment options, the pre-funded warrants, and the August Wainwright Warrants are collectively referred to as the "August Private Placement Warrants". Further, upon any exercise for cash of any preferred investment options, the Company agreed to issue to Wainwright additional warrants to purchase the number of shares of common stock equal to 6.0% of the aggregate number of shares of common stock underlying the preferred investment options that have been exercised, also with an exercise price of \$3.3938 (the "August Contingent Warrants"). The maximum number of August Contingent Warrants issuable under this provision is 298,346, which includes 70,849 of April Contingent Warrants that were modified in connection with the August Private Placement.

In connection with the August Private Placement, the Company entered into a Registration Rights Agreement with the purchasers, dated as of August 9, 2022 (the "August Registration Rights Agreement"). The August Registration Rights Agreement provides that the Company shall file a registration statement covering the resale of all of the registrable securities (as defined in the August Registration Rights Agreement) with the SEC no later than the 30th calendar day following the date of the August Registration Rights Agreement and have the registration statement declared effective by the SEC as promptly as possible after the filing thereof, but in any event no later than the 45th calendar day following August 9, 2022 or, in the event of a full review by the SEC, the 80th day following August 9, 2022. The registration statement on Form S-1 required under the Registration Rights Agreement was filed with the SEC on August 29, 2022, and became effective on September 19, 2022.

Upon the occurrence of any Event (as defined in the August Registration Rights Agreement), which, among others, prohibits the purchasers from reselling the securities for more than ten consecutive calendar days or more than an aggregate of fifteen calendar days during any 12-month period, and should the registration statement cease to remain continuously effective, the Company is obligated to pay to each purchaser, on each monthly anniversary of each such Event, an amount in cash, as partial liquidated damages and not as a penalty, equal to the product of 2.0% multiplied by the aggregate subscription amount paid by such purchaser in the August Private Placement. As of September 30, 2022, the Company determined that the likelihood of the Company incurring liquidated damages pursuant to the August Registration Rights Agreement is remote, and as such no accrual of these payments is required as of September 30, 2022.

The Company evaluated the terms of the August Private Placement Warrants and determined that they should be classified as equity instruments based upon accounting guidance provided in ASC 480 and ASC 815-40. Since the Company determined that the August Private Placement Warrants were equity-classified, the Company recorded the proceeds from the August Private Placement, net of issuance costs, within common stock at par value and the balance of the net proceeds to additional paid in capital.

As discussed above, the investors in the private placements agreed to cancel the aggregate of 1,180,812 preferred investment options issued in the April Private Placement, as part of their participation in the August Private Placement. The preferred investment options that were cancelled were effectively exchanged for 1,289,148 new preferred investment options in the August Private Placement, and accordingly have been accounted for as a modification or exchange of equity-linked instruments. In accordance with ASC 815-40, as the preferred investment options were classified as equity instruments before and after the exchange, and as the exchange is directly attributable to an equity offering, the Company recognized the effect of the exchange as an equity issuance cost. The increase in the fair value of the preferred investment options as a result of the exchange was approximately \$860,000, and was determined using the Black-Scholes option pricing model, with the following assumptions:

	<u>Original</u>	<u>Exchanged</u>
Exercise price	\$ 6.65	\$ 2.546
Term (years)	3.67	5.0
Expected stock price volatility	116.2%	120.2%
Risk-free rate of interest	3.16%	2.98%

BLUE WATER VACCINES INC.
Notes to Financial Statements

Note 6 — Stockholders' Equity (cont.)

The Company evaluated the terms of the August Contingent Warrants and determined that they should be classified as a liability based upon accounting guidance provided in ASC 815-40. As a result of the exchange of the preferred investment options issued in the April Private Placement, the underlying equity-linked instruments that would trigger issuance of the April Contingent Warrants was replaced, and therefore the 70,849 of April Contingent Warrants were exchanged for 70,849 of the August Contingent Warrants. The value of the April Contingent Warrant liability was adjusted to fair value on the date of modification, using a Monte Carlo simulation, with the change in fair value of approximately \$8,000 recognized in the accompanying condensed statements of operations. The remaining 227,497 of August Contingent Warrants were measured as a liability upon the close of the August Private Placement, and the entire 298,346 of August Contingent Warrants were remeasured at September 30, 2022, using a Monte Carlo simulation. See Note 3. Since the Contingent Warrants are a form of compensation to the placement agent, the Company recorded the value of the liability of approximately \$39,000, as a reduction of additional paid in capital, with subsequent changes in the value of the liability recorded in other income (expense) in the accompanying condensed statements of operations.

Warrants

The following summarizes activity related to the Company's outstanding warrants as discussed above, excluding contingent warrants issuable upon exercise of the preferred investment options, for the nine months ended September 30, 2022:

	Number of Shares	Weighted Average Exercise Price	Weighted Average Remaining Contractual Life (in years)
Outstanding as of December 31, 2021	—	\$ —	—
Granted	9,479,883	2.43	
Exercised	(1,535,406)	0.001	
Cancelled	(1,180,812)	6.65	
Outstanding as of September 30, 2022	<u>6,763,665</u>	2.24	4.9
Warrants vested and exercisable as of September 30, 2022	6,763,665	\$ 2.24	4.9

As of September 30, 2022, the outstanding warrants include 70,849 April Private Placement Warrants, 6,581,705 August Private Placement Warrants, and 111,111 warrants issued in connection with the IPO, which are exercisable into 6,763,665 shares of common stock which had a fair value of \$1.71 per share, based on the closing trading price on that day.

Additionally, as of September 30, 2022, the value of the April Contingent Warrants and the August Contingent Warrants (collectively the "Contingent Warrants") was approximately \$42,000, and none of the Contingent Warrants have been issued, as no preferred investment options have been exercised.

BLUE WATER VACCINES INC.
Notes to Financial Statements

Note 6 — Stockholders' Equity (cont.)

Preferred Stock

Prior to the close of the IPO, the Company had designated 1,150,000 shares of preferred stock as Series Seed Preferred Stock ("Series Seed"), with an original issue price of \$6.09 per share (the "Original Issue Price"). As of September 30, 2022 and December 31, 2021, there were 0 and 1,146,138 shares issued and outstanding, respectively.

Conversion

Each share of the Series Seed was convertible, at the option of the holder, at any time and from time to time, and without the payment of additional consideration by the holder, at a conversion price of \$1.52 per share, subject to certain adjustments for stock splits, stock dividends, recapitalizations, and similar corporate transactions, into fully paid and non-assessable shares of the Company's common stock. Each Series Seed share was automatically convertible into common stock of the Company, at the then-effective conversion price, upon the closing of 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. On February 18, 2022, the majority of the holders of the Series Seed approved the automatic conversion of the outstanding shares of the Series Seed and all related accrued and unpaid dividends, upon the close of the IPO. The number of conversion shares to be issued upon the close of the IPO were to be calculated in accordance with the original conversion terms provided by the Company's Amended and Restated Certificate of Incorporation ("COI") dated July 1, 2019. This conversion occurred on February 23, 2022, upon the close of the Company's IPO.

Dividends

Holders of the Series Seed were entitled to receive cumulative dividends at a per share rate of 8% per annum, compounded annually, on the initial investment amount commencing on the date of issue. Dividends were payable only when, as, and if declared by the Board of Directors or upon a Liquidation Event, as described below. Dividends on Series Seed were in preference to any dividend on the Company's common stock. Upon the close of the IPO, aggregate cumulative dividends of \$1,586,162 or \$1.38 per Series Seed share were automatically converted into shares of common stock.

Liquidation Preference

In the event of certain voluntary or involuntary acquisition or sale transactions or upon the liquidation, dissolution or winding up of the Company (each, a "Liquidation Event"), the holders of Series Seed were entitled to receive out of the proceeds or assets of the Company legally available for distribution to its stockholders (the "Proceeds"), prior and in preference to any distribution of the Proceeds of such Liquidation Event to the holders of shares of common stock by reason of their ownership thereof, an amount ("the Liquidation Preference Amount") determined based on the provisions of the Company's COI. The COI provided that the Liquidation Preference Amount be calculated upon the occurrence of a Liquidation Event, based on the Company's achievement of a Pre-Clinical Milestone and a Qualified Financing, both as defined in the COI. Per the provisions of the COI, if a Liquidation Event occurred before a Pre-Clinical Milestone was achieved, the Liquidation Preference Amount would be equal to two times the Series Seed Original Issue price per share, plus unpaid cumulative dividends. If a Liquidation Event occurred after a Pre-Clinical Milestone was achieved, and after a Qualified Financing was completed, then the Liquidation Preference Amount would be equal to one times the Series Seed Original Issue price, plus unpaid cumulative dividends. If a Liquidation Event occurred after a Pre-Clinical Milestone was achieved and before a Qualified Financing was completed, the Liquidation Preference Amount would be equal to the greater of (a) such amount per share as such holder would have been entitled to receive after a Qualified Financing or (b) two times the Series Seed Original Issue price, plus unpaid cumulative dividends.

As of December 31, 2021, and all other prior historical periods, the Liquidation Preference Amount was equal to two times the Series Seed Original Issue Price per share, plus unpaid cumulative dividends. In the event that the Proceeds were insufficient to enable the distribution in full of the Liquidation Preference Amount to the holders of the Series Seed for all of the preferred shares held by them, all of the Proceeds were to be distributed among the holders of Series Seed on a pro rata basis. Upon completion of the distribution required to the holders of Series Seed, all of the remaining Proceeds available for distribution to stockholders were to be distributed among the holders of common shares and preferred shares, on an as-converted basis, pro rata based on the number of common shares held by each such holder. However, if upon the occurrence of a Liquidation Event, the Liquidation Preference Amount the Series Seed stockholders were entitled to receive is two times the Original Issue Price per share, plus unpaid cumulative dividends, after such distribution is made, then the remaining Proceeds available for distribution to stockholders were to be distributed among the holders of common shares, pro rata based on the number of common shares held by each such holder.

Voting

On any matter presented to the stockholders of the Company for their action or consideration at any meeting of stockholders of the Company (or by written consent of stockholders in lieu of meeting), each holder of outstanding shares of Series Seed were entitled to cast the number of votes equal to the number of whole shares of common stock into which the shares of Series Seed held by such holder were convertible as of the record date for determining stockholders entitled to vote on such matter. Holders of Series Seed were entitled to vote together with the holder of common stock as a single class. Holders of Series Seed were entitled to nominate two out of five of the Company's directors.

BLUE WATER VACCINES INC.
Notes to Financial Statements

Note 6 — Stockholders' Equity (cont.)

Equity Incentive Plans

The Company's 2019 Equity Incentive Plan (the "2019 Plan") was adopted by its board of directors and by its stockholders on July 1, 2019. The Company has reserved 1,400,000 shares of common stock for issuance pursuant to the 2019 Plan. There were no share-based awards granted under the 2019 Plan during the three and nine months ended September 30, 2022 and 2021.

In addition, on February 23, 2022 and in connection with the closing of the IPO, the Company's board of directors adopted the Company's 2022 Equity Incentive Plan (the "2022 Plan"), which is the successor and continuation of the Company's 2019 Plan. Under the 2022 Plan, the Company may grant stock options, restricted stock, restricted stock units, stock appreciation rights, and other forms of awards to employees, directors and consultants of the Company. Upon its effectiveness, a total of 1,600,000 shares of common stock were reserved for issuance under the 2022 Plan. In August 2022, the number of shares of common stock reserved for issuance under the 2022 Plan was increased to 2,600,000. The stock options granted during the three and nine months ended September 30, 2022 were all granted under the 2022 Plan. As of September 30, 2022, there are 1,050,747 options available for issuance under the 2022 Plan.

Stock Options

The following summarizes activity related to the Company's stock options under the 2019 Plan and the 2022 Plan for the nine months ended September 30, 2022:

	Number of Shares	Weighted Average Exercise Price	Total Intrinsic Value	Weighted Average Remaining Contractual Life (in years)
Outstanding as of December 31, 2021	780,640	\$ 0.01	\$ 532,787	8.1
Granted	768,613	6.10	—	—
Forfeited / cancelled	—	—	—	—
Exercised	(165,452)	0.01	573,465	—
Outstanding as of September 30, 2022	<u>1,383,801</u>	3.40	\$ 1,044,282	8.6
Options vested and exercisable as of September 30, 2022	847,081	\$ 3.13	\$ 735,622	8.4

The fair value of options granted in 2022 was estimated using the following assumptions:

	For the Three Months Ended September 30, 2022	For the Nine Months Ended September 30, 2022
Exercise price	\$ 2.91 – 3.48	\$ 2.55 – 6.45
Term (years)	5.04 – 7.00	5.00 – 10.00
Expected stock price volatility	114.8% – 119.9%	114.5% – 121.2%
Risk-free rate of interest	3.2% – 3.5%	2.9% – 3.5%

The weighted average grant date fair value of stock options granted during the three and nine months ended September 30, 2022 was \$2.55 and \$3.49, respectively. The aggregate fair value of stock options that vested during the three and nine months ended September 30, 2022 was approximately \$0.4 million and \$1.9 million, respectively.

Of the total stock options granted during the nine months ended September 30, 2022, 200,000 stock options were granted to the Company's Chief Executive Officer ("CEO"), Chairman, and significant stockholder, 200,000 stock options were granted to the Company's Chief Business Officer ("CBO"), and 100,000 stock options were granted to the Company's Chief Financial Officer ("CFO"). The aggregate grant-date fair value of the stock options granted to the CEO, CBO, and CFO during the nine months ended September 30, 2022 was approximately \$1.8 million, of which approximately \$0.2 million and \$1.4 million was recognized as stock-based compensation expense during the three and nine months ended September 30, 2022, respectively. Additionally, during the three and nine months ended September 30, 2022, the Company granted an aggregate of 4,073 and 68,613 stock options, respectively, to non-executive directors. The grant-date fair value of the stock options granted to the non-executive directors was approximately \$12,000 and \$0.2 million for the three and nine months ended September 30, 2022, respectively, of which approximately \$46,000 and \$0.1 million was recognized as stock-based compensation expense during the three and nine months ended September 30, 2022, respectively.

During the three and nine months ended September 30, 2022, the Company's board of directors approved the accelerated vesting of an aggregate of 19,109 stock options to a former director, in connection with the director's separation from the Company. The Company recognized stock-based compensation expense of approximately \$48,000 related to this modification during the three and nine months ended September 30, 2022.

BLUE WATER VACCINES INC.
Notes to Financial Statements

Note 6 — Stockholders' Equity (cont.)

Stock-Based Compensation

Stock-based compensation expense for the three and nine months ended September 30, 2022 and 2021 was as follows:

	For the Three Months Ended		For the Nine Months Ended	
	September 30,		September 30,	
	2022	2021	2022	2021
General and administrative	\$ 255,115	\$ 9,337	\$ 1,193,743	\$ 33,213
Research and development	74,694	19,971	602,525	72,740
Total	\$ 329,809	\$ 29,308	\$ 1,796,268	\$ 105,953

As of September 30, 2022, unrecognized stock-based compensation expense relating to outstanding stock options is approximately \$1.0 million, which is expected to be recognized over a weighted-average period of 2.02 years.

Note 7 — Commitments and Contingencies

Office Leases

Starting in 2018, the Company leased office space for approximately \$5,500 a month from a related party. The Company was required to pay a \$15,000 rental deposit. Rent expense related to this lease for the three and nine months ended September 30, 2022 was \$0. Rent expense related to this lease for the three and nine months ended September 30, 2021 was approximately \$0 and \$28,000, respectively. The Company terminated the related party lease in May 2021 and entered into a month-to-month lease in Cincinnati, Ohio, with an unrelated party in April 2021 with monthly payments of approximately \$500 per month.

The Company entered into a short-term lease in Palm Beach, Florida with an unrelated party, with a commencement date of May 1, 2022, for approximately \$14,000 per month. The lease term ends on April 30, 2023 and is personally guaranteed by the Company's CEO. The Company incurred rent expense for the three and nine months ended September 30, 2022 of approximately \$53,000 and \$89,000, respectively.

Litigation

From time to time, the Company may be subject to various legal proceedings and claims that arise in the ordinary course of its business activities. As of September 30, 2022, the Company is not a party to any material legal proceedings and is not aware of any pending or threatened claims aside from the following.

On April 15, 2022, the Company received a demand letter (the "Demand Letter") from Boustead. The Demand Letter alleged that the Company breached the Underwriting Agreement entered into between Boustead and the Company, dated February 17, 2022, in connection with the Company's initial public offering. The Demand Letter alleged that, by engaging Wainwright as placement agent in the April Private Placement, the Company breached Boustead's right of first refusal ("ROFR") to act as placement agent granted to Boustead under the Underwriting Agreement and, as a result of selling securities in the April Private Placement, breached the Company's obligation under the Underwriting Agreement not to offer, sell, issue, agree or contract to sell or issue or grant or modify the terms of any option for the sale of, any securities prior to February 17, 2023 (the "Standstill").

On October 9, 2022, the Company and Boustead entered into a Settlement Agreement and Release (the "Settlement Agreement"), pursuant to which Boustead agreed to waive the ROFR and the Standstill, and to release the Company from certain claims with respect to the April Private Placement, the August Private Placement, and all future private, public equity or debt offerings of the Company. As consideration for such waiver and termination of the Underwriting Agreement, the Company agreed to pay Boustead a cash fee of \$1,000,000, \$50,000 in legal expenses, and release Boustead from all claims, subject to certain exceptions. In addition, the Company agreed to issue to Boustead 93,466 shares of restricted common stock in exchange for the cancellation of 111,111 warrants issued to Boustead in connection with the IPO (see Note 6). Concurrent with the execution of the Settlement Agreement, the Company and Boustead Capital Markets, LLP ("Boustead Capital") entered into a three-month Advisory Agreement (the "Advisory Agreement") for which consideration equal to 200,000 shares of restricted common stock, with no vesting provisions, was issuable to Boustead Capital upon execution of the Advisory Agreement.

The Company evaluated the related contingency in accordance with authoritative guidance, and determined that all consideration due by the Company under the Settlement Agreement and the Advisory Agreement relates to the settlement of a liability that was incurred as of September 30, 2022, and therefore the Company recognized approximately \$1.3 million as an accrued loss contingency in the accompanying condensed balance sheet as of September 30, 2022. The restricted common stock exchanged for the cancellation of the warrants was accounted for as a modification of the warrant, with the incremental fair value of approximately \$10,000 recorded as part of the consideration. In addition, the total consideration includes approximately \$254,000 for the fair value of the 200,000 shares of restricted common stock that were issued upon execution of the Advisory Agreement. The restricted common stock issuable under the Settlement Agreement and the Advisory Agreement was valued based on the closing trading price on the date the agreements were executed, adjusted to reflect the effect of the restriction on the sale of the common stock. The value of the restriction was measured using the Black-Scholes model to measure the discount for lack of marketability, using the following assumptions: expected term of 0.5 years, expected volatility of 96.36%, risk-free interest rate of 4.09% and dividend yield of 0.0%.

The Company has recorded a related expense of approximately \$0.8 million and \$1.3 million for the three and nine months ended September 30, 2022, respectively, which is included in general and administrative expense in the accompanying condensed statements of operations.

BLUE WATER VACCINES INC.
Notes to Financial Statements

Note 7 — Commitments and Contingencies (cont.)

Registration Rights Agreement

See Note 6.

Significant Agreements

Oxford University Innovation Limited

Pursuant to the OUI Agreement, as disclosed in Note 5, the Company is obligated to pay certain milestone and royalty payments in the future, as the related contingent events occur. Specifically, the Company is obligated to pay a 6% royalty on all net sales of licensed products, as defined in the OUI Agreement, with an annual minimum royalty payment of \$250,000 starting post-product launch, until the expiration of the OUI Agreement or revocation of the last valid claim covering a licensed product, at which point a royalty rate of 3% will apply. An annual maintenance fee of \$10,000 and \$20,000 is required in the pre-phase III year and Phase III year, respectively, and as defined in the OUI Agreement. The Company is also obligated to pay a 25% royalty on any sums received by the Company from any sublicensee (including all up-front, milestone and other one-off payments received by the Company from any sub-licenses or other contracts granted by the Company with respect to the licensed technology). In addition, the Company is required to pay OUI milestone payments of up to an aggregate of \$51.25 million; specifically, upon the achievement of specified development milestones of approximately \$2.25 million, regulatory milestones of approximately \$9.5 million, and commercial milestones of approximately \$39.5 million. The annual maintenance fee and milestone fees are indexed to the RPI (Retail Prices index for all items which is published in the United Kingdom by the Office for National Statistics, or any replacement of it) and will be increased or decreased as appropriate as set forth in the OUI Agreement. As of September 30, 2022, the Company evaluated the likelihood of the Company achieving the specified milestones and generating product sales, and determined the likelihood is not yet probable and as such no accrual of these payments is required as of September 30, 2022.

Oxford University Research Agreement

Pursuant to the terms of the OUI Agreement, as disclosed in Note 5, the Company entered into a sponsored research agreement dated December 18, 2019 with Oxford University for research related to the OUI Agreement for a period of three years for a total of £420,000. The Company prepaid the full amount to Oxford of \$554,802 for the services in January 2020, of which approximately \$0.2 million remains as a prepaid expense as of September 30, 2022 and December 31, 2021. On May 16, 2022, the Company entered into an amendment to the Oxford University Research Agreement, whereby the Oxford University Research Agreement was extended until June 30, 2024, with an option to extend another 12 months, for a fee of £53,500 (or approximately \$56,000).

St. Jude Children's Hospital

Pursuant to the St. Jude Agreement, as disclosed in Note 5, the Company is obligated to pay certain milestone and royalty payments in the future, as the related contingent events occur. On May 11, 2022, the Company entered into an amendment to the St. Jude Agreement, whereby the royalty terms, milestones payments and licensing fees were amended. Specifically, pursuant to the terms of the St. Jude Agreement, as amended, the Company is obligated to make 5% royalty payments for each licensed product(s) sold by the Company or its affiliates, based on the net sales for the duration of the St. Jude Agreement, and also pay 15% of consideration received for any sublicenses. The Company is also required to pay an additional one-time \$5,000 license fee, and an annual maintenance fee of \$10,000 beginning on the first anniversary of the Effective Date (which is waived if all of the developmental milestones scheduled for completion before such annual fee is due have been achieved). In addition, the Company is required to pay St. Jude milestone payments of up to an aggregate of \$1.9 million; specifically, upon the achievement of specified development milestones of \$0.3 million, regulatory milestones of \$0.6 million, and commercial milestones of \$1.0 million. As of September 30, 2022, the Company evaluated the likelihood of the Company achieving the specified milestones and generating product sales, and determined the likelihood is not yet probable and as such no accrual of these payments is required as of September 30, 2022.

St. Jude Children's Sponsored Research Agreement

In addition to the St. Jude Agreement, the Company also entered into a sponsored research agreement dated May 3, 2021 with St. Jude for research related to the St. Jude Agreement (the "St. Jude SRA"). Pursuant to the St. Jude SRA, the Company is obligated to pay St. Jude an aggregate amount of \$73,073 in two parts, Phase I for \$57,624 and Phase II for \$15,449. This sponsored research project began during 2021, and the Company recorded approximately \$8,000 in related accrued expenses at December 31, 2021.

The Company entered into a second sponsored research agreement with St. Jude, dated August 29, 2022, pursuant to which the Company is obligated to pay St. Jude an amount of \$75,603 which is due within 30 days of the effective date of the agreement.

During the three and nine months ended September 30, 2022, the Company incurred related research and development expenses related to the sponsored research agreements with St. Jude of approximately \$8,000 and \$15,000, respectively, and had approximately \$8,000 recorded in accrued expenses at September 30, 2022. During the three and nine months ended September 30, 2021, the Company incurred related research and development expenses of approximately \$0 and \$58,000, respectively.

BLUE WATER VACCINES INC.
Notes to Financial Statements

Note 7 — Commitments and Contingencies (cont.)

Cincinnati Children’s Hospital Medical Center

Pursuant to the CHMC Agreement, as disclosed in Note 5, the Company is obligated to pay certain milestone and royalty payments in the future, as the related contingent events occur. Specifically, the Company is obligated to pay CHMC a single-digit royalty on net sales, being 5%, 4% or 2% depending on the product, until the last valid claim covering a licensed product exists, at which point the royalty rates decrease by 50%. The Company is also obligated to pay up to a 25% royalty on any non-royalty sublicense revenue paid to the Company by any sublicensee. The CHMC Agreement also provides the Company with an option to license any CHMC or jointly patented modification, alteration or improvement of any invention claimed in a Licensed Patent (“CHMC Improvement” and “Joint Improvement, respectively”), with a \$50,000 option fee for each Improvement that the Company elects to include in the license grant of the CHMC Agreement. In addition, the Company is required to pay CHMC milestone payments of up to an aggregate of \$59.75 million; specifically, upon the achievement of specified development milestones of approximately \$0.5 million, regulatory milestones of approximately \$1.25 million, and commercial milestones of approximately \$58 million. As of September 30, 2022, the Company evaluated the likelihood of the Company achieving the specified milestones and generating product sales, and determined the likelihood is not yet probable and as such no accrual of these payments is required as of September 30, 2022.

CHMC Sponsored Research Agreement

In addition to the CHMC Agreement, the Company also entered into a sponsored research agreement dated June 30, 2022 with CHMC for research related to the CHMC Agreement (the “CHMC SRA”). Pursuant to this research agreement, the Company is obligated to pay CHMC an aggregate amount not-to-exceed \$247,705. The CHMC SRA has a term of one year, and is cancelable upon 60 days written notice by either party for convenience. In addition, either party may terminate the CHMC SRA in the event the other party (a) files or has filed against it a petition under the Bankruptcy Act (among other things) or (b) fails to perform or otherwise breaches its obligations under the agreement, and has not cured such failure or breach within 30 days of notice of material breach. During the three and nine months ended September 30, 2022, the Company incurred related research and development expenses of approximately \$37,000, which was included in accrued expenses at September 30, 2022. There were no such expenses incurred during the three and nine months ended September 30, 2021.

Ology Bioservices, Inc. (which was later acquired by National Resilience, Inc.)

Pursuant to the Ology MSA and the second Project Addendum, as disclosed in Note 5, the Company is obligated to pay Ology an aggregate amount of approximately \$2.8 million, plus reimbursement for materials and outsourced testing which will be billed at cost plus 15%. This project began during 2021, and the Company recorded approximately \$164,000 and \$115,000 as related accounts payable and accrued expenses, respectively, at December 31, 2021.

On April 20, 2022, the Company entered into an amendment to the Ology MSA, whereby the Company’s obligations increased by \$300,000, specifically related to regulatory support on the project. During the three and nine months ended September 30, 2022, the Company incurred related research and development expenses of approximately \$496,000 and \$988,000, respectively, and had approximately \$53,000 and \$851,000 recorded as related accounts payable and accrued expenses, respectively, at September 30, 2022. There was approximately \$71,000 of related expenses incurred during the three and nine months ended September 30, 2021. This project is currently expected to be performed through the fourth quarter of 2023.

Underwriter Termination Agreement

On February 7, 2022, the Company and its former underwriter, Maxim Group (“Maxim”), entered into a termination agreement, whereby the parties agreed to terminate their engagement of Maxim as the Company’s lead managing underwriter and book runner in connection with the Company’s IPO. Per the terms of the termination agreement, the Company agreed to pay Maxim a termination fee of \$300,000, due upon the close of the Company’s IPO. The termination fee was recorded as general and administrative expense, and paid, during the nine months ended September 30, 2022.

Indemnification

In the normal course of business, the Company enters into contracts and agreements that contain a variety of representations and warranties and provide for general indemnifications. The Company’s exposure under these agreements is unknown because it involves claims that may be made against the Company in the future but have not yet been made. To date, the Company has not paid any claims or been required to defend any action related to its indemnification obligations. However, the Company may incur charges in the future as a result of these indemnification obligations.

Risks and Uncertainties — COVID-19

Management continues to evaluate the impact of the COVID-19 pandemic on the industry and has concluded that while it is reasonably possible that the virus could have a negative effect on the Company’s financial position, results of its operations and/or search for drug candidates, the specific impact is not readily determinable as of the date of these financial statements. The financial statements do not include any adjustments that might result from the outcome of this uncertainty.

BLUE WATER VACCINES INC.
Notes to Financial Statements

Note 8 — Related Party Transactions

The Company originally engaged the CEO, who is also the Board Chairman and prior to the close of the IPO, sole common stockholder of the Company, pursuant to a consulting agreement commencing October 22, 2018, which called for the Company to pay for consulting services performed on a monthly basis. Upon the close of the Company's IPO, the consulting agreement was terminated and the CEO's employment agreement became effective. During the three and nine months ended September 30, 2022, the Company incurred approximately \$0 and \$63,000 in fees under the consulting agreement, respectively, which are recognized in general and administrative expenses in the accompanying condensed statements of operations. During the three and nine months ended September 30, 2021, the Company incurred approximately \$105,000 and \$315,000 in fees under the consulting agreement, respectively, which are recognized in general and administrative expenses in the accompanying condensed statements of operations.

The Company also leased office space from a related party, through common ownership. The lease is further described in Note 7 of these financial statements. The lease was terminated in May 2021, and the related deposit was reclassified to the receivable from related party balance.

During the nine months ended September 30, 2022, the Company's compensation committee approved one-time bonus awards of \$140,000 and \$100,000 to the Company's CEO and CBO, respectively, in recognition of their efforts in connection with the Company's IPO. These bonuses were recognized during the nine months ended September 30, 2022 as general and administrative expenses in the accompanying condensed statements of operations. In addition, during the three and nine months ended September 30, 2022, the Company's compensation committee approved stock option grants under the Company's 2022 Equity Incentive Plan to certain of the Company's executive officers. See Note 6.

As of September 30, 2022 and December 31, 2021, the Company has a receivable from related party of approximately \$35,000 and \$153,000, respectively. The balance as of September 30, 2022 consists of miscellaneous payments made by the Company on the behalf of the Company's CEO. The CEO paid the Company approximately \$14,000 of the receivable balance in October 2022. The balance as of December 31, 2021, consists primarily of consulting fee prepayments to the Company's CEO, in the amount of \$140,000. These consulting fee prepayments were repaid to the Company in lieu of a bonus payout due to the CEO during May 2022. The remaining balance as of December 31, 2021 consists of miscellaneous payments made by the Company on the behalf of the CEO.

One of the Company's former directors and current Scientific Advisory Board members serves on the Advisory Board for the Cincinnati Children's Hospital Medical Center Innovation Fund, which is affiliated with CHMC. The Company has an exclusive license agreement with CHMC as disclosed in Note 5. This director resigned from the Company's board upon the close of its IPO.

Note 9 — Income Taxes

No provision for federal, state or foreign income taxes has been recorded for the three and nine months ended September 30, 2022 and 2021. The Company has incurred net operating losses for all of the periods presented and has not reflected any benefit of such net operating loss carryforwards in the accompanying condensed financial statements due to uncertainty around utilizing these tax attributes within their respective carryforward periods. The Company has recorded a full valuation allowance against all of its deferred tax assets as it is not more likely than not that such assets will be realized in the near future. The Company's policy is to recognize interest expense and penalties related to income tax matters as income tax expense. For the three and nine months ended September 30, 2022 and 2021, the Company has not recognized any interest or penalties related to income taxes.

Note 10 — Retirement Plan

Effective January 1, 2022, the Company adopted a defined contribution savings plan pursuant to Section 401(k) of the Internal Revenue Code ("the 401(k) Plan"). The 401(k) Plan is for the benefit of all qualifying employees and permits voluntary contributions by employees of up to 100% of eligible compensation, subject to the maximum limits imposed by the Internal Revenue Service. The terms of the 401(k) Plan allow for discretionary employer contributions. No expenses were incurred related to the 401(k) Plan during the three and nine months ended September 30, 2022, and the 401(k) Plan lapsed during the nine months ended September 30, 2022 due to inactivity.

Note 11 — Subsequent Events

On October 9, 2022, the Company and Boustead entered into a Settlement Agreement and Release (the "Settlement Agreement") pursuant to which Boustead agreed to waive certain obligations of the Company under the Underwriting Agreement that was entered into between the two parties in connection with the Company's IPO in February 2022. As consideration for such waiver and termination of the Underwriting Agreement, the Company agreed to pay Boustead a cash fee of \$1,000,000, \$50,000 in legal expenses, and release Boustead from all claims, subject to certain exceptions. In addition, the Company agreed to issue to Boustead 93,466 shares of restricted common stock in exchange for the cancellation of 111,111 warrants issued to Boustead in connection with the IPO. Concurrent with the execution of the Settlement Agreement, the Company and Boustead entered into a three-month Advisory Agreement for which consideration equal to 200,000 shares of restricted common stock, with no vesting provisions, was issuable to Boustead Capital upon execution of the Advisory Agreement. See Note 7.

On October 4, 2022, 491,640 of the Pre-Funded Warrants issued in connection with the August Private Placement were exercised, at an exercise price of \$0.001 per share, and as such the Company issued 491,640 shares of common stock on that date.

On November 4, 2022, the Company's Board of Directors (the "Board") appointed a new Class I Director to replace a director who resigned from the Board on the same day. The new Class I Director was also appointed to the Compensation Committee of the Board and the Nomination and Corporate Governance Committee of the Board. On November 8, 2022, the Board granted 3,610 stock options to the new Class I Director, with an exercise price of \$1.06.

On November 10, 2022, the Board approved a share repurchase program to allow for the Company to repurchase up to 5 million shares with a maximum price of \$1.00 per share, with discretion to management to make purchases subject to market conditions.

Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations.

The following discussion and analysis of our financial condition and results of operations should be read in conjunction with our financial statements and the related notes to those statements included elsewhere in this Quarterly Report on Form 10-Q and with the audited financial statements and the related notes included in our Annual Report on Form 10-K for the fiscal year ended December 31, 2021, as filed with the SEC, on March 31, 2022. In addition to historical financial information, the following discussion and analysis contains forward-looking statements that involve risks, uncertainties, and assumptions. Some of the numbers included herein have been rounded for the convenience of presentation. Our actual results may differ materially from those anticipated in these forward-looking statements as a result of many factors. See "Cautionary Note Regarding Forward-Looking Statements."

Overview

We are a biotechnology company focused on the research and development of transformational vaccines to prevent infectious diseases worldwide. Our versatile vaccine platform has unique molecular properties that enables delivery of various antigens, which can be utilized to develop singular or multi-targeted vaccines. Our lead influenza (flu) vaccine program uses proprietary technology to identify specific epitopes, or proteins of antigens, with cross-reactive properties, that enable the potential development of a universal flu vaccine. We are focused on developing novel vaccines that induce durable and long-term immunity. We believe that our pipeline and vaccine platform are synergistic for developing next generation preventive vaccines to improve both health outcomes and quality of life globally.

Since June 30, 2022, key development affecting our business include:

- **Completed Successful \$8.7 Million Private Placement:** In the third quarter of 2022, we completed a private placement of 1,350,000 shares of common stock and pre-funded warrants to purchase an aggregate of 2,333,280 shares of common stock. The aggregate net cash proceeds to us from the offering were \$8.7 million, after deducting placement agent fees and other offering expenses.
- **Expanded Acute Otitis Media (AOM) Candidate, BWV-201, Indication to Include Pneumococcal Pneumonia:** Based on data generated by Jason Rosch, Ph.D., at St. Jude Children's Research Hospital, we announced plans to evaluate efficacy and immunogenicity of BWV-201 in pneumococcal pneumonia at the World Vaccine Congress Europe 2022. Current vaccines do not provide adequate protection against pneumonia induced by *Streptococcus pneumoniae* given their limitation to serotypes included in the vaccine and inability to provide mucosal immunity, while serotype-independent and intranasally delivered BWV-201 is hypothesized to protect against pneumococcal pneumonia regardless of bacterial subtype and provide strong mucosal immunity.
- **Initiated Research Plans to Investigate VLP Platform Applicability for a Novel Monkeypox Vaccine:** In the third quarter of 2022, we announced research plans to investigate the ability to present monkeypox antigens within the norovirus shell & protrusion (S&P) VLP platform to create a novel monkeypox vaccine candidate.
- **Signing of Sponsored Research Agreement with Cincinnati Children's Hospital Medical Center for VLP Research:** We entered into a Sponsored Research Agreement with licensing partner, Cincinnati Children's Hospital Medical Center, to assess the ability for the Company's virus-like particle (VLP) platform to develop vaccines for various diseases, including influenza and Alzheimer's disease. For influenza, this agreement initiates the integration of the epitopes of limited variability identified at The University of Oxford into this platform for the development of a novel influenza vaccine candidate.
- **Announced Simon Tarsh to the Board of Directors:** At the Company's Annual Meeting in August 2022, we announced the appointment of Simon Tarsh to the Blue Water Vaccines Board of Directors. Mr. Tarsh brings significant financial consulting experience to the board, most recently serving as a Senior Managing Director in the Finance and Enterprise Performance Practice at Deloitte Consulting.

- **Presented Vaccine Candidate Progress at Various Scientific Conferences:** We have participated in multiple scientific conferences detailing the progress for our vaccine candidates, including disease-specific conferences to showcase our technologies. In September 2022, Sunetra Gupta, Ph.D., Professor of Theoretical Epidemiology at The University of Oxford and current member of the BWV Scientific Advisory Board, presented BWV's approach to develop a universal flu vaccine, BWV-101, at The Universal Influenza Vaccines 2022 Conference in Oxford, United Kingdom. In addition, we presented this approach and hosted a roundtable event to discuss the importance of mathematical modeling, used to invent BWV-101, within vaccine development at the World Vaccine Congress Europe 2022.
- **Presented Company Overview at Various Conferences:** We continue to develop relationships with the investment community through directed outreach. We were invited to present at the H.C. Wainwright Global Investment Conference in September 2022 and the LD Micro Main Event XV in October 2022 to present our company overview and vaccine candidate pipeline to key stakeholders within the investment community.

An updated summary of the Company's pipeline for all vaccine candidates is provided as follows:

Infectious Disease Program	Candidate	Preclinical	Phase 1	Phase 2	Phase 3	Collaborator
<i>S. pneumo</i> -Induced Acute Otitis Media & Pneumonia	BWV-201					
Universal Flu	BWV-101					
H1N1 Pre-Pandemic	BWV-102					
Norovirus / Rotavirus	BWV-301					
Norovirus / Malaria	BWV-302					

Since our inception in October 2018, we have devoted substantially all of our resources to performing research and development, undertaking preclinical studies and enabling manufacturing activities in support of our product development efforts, hiring personnel, acquiring and developing our technology and vaccine candidates, organizing and staffing our company, performing business planning, establishing our intellectual property portfolio and raising capital to support and expand such activities. We do not have any products approved for sale and have not generated any revenue from product sales. To date, we have financed our operations primarily with proceeds from our sale of preferred securities to seed investors, the close of our initial public offering, and the close of our private placements. We will continue to require additional capital to develop our vaccine candidates and fund operations in the long-term. Accordingly, until such time as we can generate significant revenue from sales of our vaccine candidates, if ever, we expect to finance our cash needs through public or private equity or debt financings, third-party (including government) funding and marketing and distribution arrangements, as well as other collaborations, strategic alliances and licensing arrangements, or any combination of these approaches.

We have incurred net losses since inception and expect to continue to incur net losses in the foreseeable future. Our net losses may fluctuate significantly from quarter-to-quarter and year-to-year, depending in large part on the timing of our preclinical studies, clinical trials and manufacturing activities, and our expenditures on other research and development activities. As of September 30, 2022, the Company had working capital of approximately \$25.6 million and an accumulated deficit of approximately \$16.2 million. We will need to raise additional capital to sustain operations and meet our long-term operating requirements beyond the one-year period following the issuance of the accompanying condensed financial statements.

While we believe that we can raise additional capital to fund our planned operations, until we generate revenue sufficient to support self-sustaining cash flows, if ever, we will need to raise additional capital to fund our continued operations to execute our long-term business plan, including our product development and commercialization activities related to our current and future products. There can be no assurance that additional capital will be available to us on acceptable terms, or at all, or that we will ever generate revenue sufficient to provide for self-sustaining cash flows.

We do not expect to generate any revenue from commercial product sales unless and until we successfully complete development and obtain regulatory approval for one or more of our vaccine candidates, which we expect will take a number of years. We expect our expenses will increase substantially in connection with our ongoing activities, as we:

- advance vaccine candidates through preclinical studies and clinical trials;
- require the manufacture of supplies for our preclinical studies and clinical trials;
- pursue regulatory approval of vaccine candidates;
- hire additional personnel;
- operate as a public company;
- acquire, discover, validate and develop additional vaccine candidates; and
- obtain, maintain, expand and protect our intellectual property portfolio.

We rely and will continue to rely on third parties in the conduct of our preclinical studies and clinical trials and for manufacturing and supply of our vaccine candidates. We have no internal manufacturing capabilities, and we will continue to rely on third parties, of which the main suppliers are single-source suppliers, for our preclinical and clinical trial materials. Given our stage of development, we do not yet have a marketing or sales organization or commercial infrastructure. Accordingly, if we obtain regulatory approval for any of our vaccine candidates, we also expect to incur significant commercialization expenses related to product sales, marketing, manufacturing and distribution.

Because of the numerous risks and uncertainties associated with vaccine development, we are unable to predict the timing or amount of increased expenses or when or if we will be able to achieve or maintain profitability. Even if we are able to generate revenue from the sale of our vaccines, we may not become profitable. If we fail to become profitable or are unable to sustain profitability on a continuing basis, then we may be unable to continue our operations at planned levels and may be forced to reduce our operations.

Certain Significant Relationships

We have entered into grant, license and collaboration arrangements with various third parties as summarized below. For further details regarding these and other agreements, see Note 5 to each of our audited financial statements included in the Form 10-K and unaudited financial statements included elsewhere in this Report.

Ology Agreement

In July 2019, we entered into a development and manufacturing master services agreement with Ology Bioservices (which was later acquired by National Resilience, Inc.) (“Ology”), as amended, which we refer to as the Ology Agreement, pursuant to which Ology is obligated to perform manufacturing process development and clinical manufacture and supply of components.

Under the Ology Agreement, we will pay Ology agreed upon fees for Ology’s performance of manufacturing services and regulatory support, and we will reimburse Ology for its out-of-pocket costs associated with purchasing raw materials, plus a customary handling fee.

On April 20, 2022, the Company and Ology entered into an amendment to the second Project Addendum (the “Ology Amendment”). The Ology Amendment provides for an increase to the Company’s obligation of \$0.3 million, specifically related to regulatory support on the project.

On August 30, 2022, the Company and Ology entered into another amendment to the second Project Addendum, which provides for a decrease to the Company’s obligation of \$0.4 million, as a result of the change in the scope of work comprising certain tasks defined in the second Project Addendum.

For additional details regarding our relationship with Ology, see Notes 5 and 7 to our financial statements included elsewhere in this Report.

Cincinnati Children’s Hospital Medical Center Agreement

On June 1, 2021, we entered into an exclusive, worldwide license agreement with Children’s Hospital Medical Center, d/b/a Cincinnati Children’s Hospital Medical Center, or CHMC, which we refer to as the CHMC Agreement, pursuant to which we obtained the right to develop and commercialize certain CHMC patents and related technology directed at a virus-like particle (VLP) vaccine platform that utilizes nanoparticle delivery technology, which may have potential broad application to develop vaccines for multiple infectious diseases.

Under the CHMC Agreement, we agreed to pay CHMC certain license fees, deferred license fees, development milestone fees, and running royalties beginning on the first net sale (among others). For additional details regarding our relationship with CHMC, see Note 5 to our financial statements included elsewhere in this Report. The CHMC license includes the following patents:

U.S. Patent Application No.	U.S. Patent No.	Granted Claim Type	U.S. Expiration	Foreign Counterparts
12/797,396	8,486,421	Compositions of the vaccine/vaccine platform	1/13/2031	CN107043408B EP2440582B1 JP5894528B2
13/924,906	9,096,644	Method of treatment	9/20/2030	CN107043408B EP2440582B1 JP5894528B2
13/803,057	9,562,077	Compositions of the vaccine platform	4/10/2034	none
16/489,095	pending	pending	[3/15/2038]*	Pending applications in Canada, China, EU and Japan
63/149,742 (filed 2/16/2021)	pending	pending	[February 2042]#	TBD
63/162,369 (filed 3/17/2021)	pending	pending	[March 2042]#	TBD

* Projected expiration if patent issues: 20 years from earliest non-provisional application filing date.

Non-provisional application not yet filed. Expiration projected 21 years from provisional application filing date. Dependent on timely conversion to non-provisional application and issuance of patent.

** This is a pending application. Claim type will be determined after U.S. prosecution is complete. The claim type sought includes compositions of the vaccine and vaccine platform.

CHMC Sponsored Research Agreement

In addition to the CHMC Agreement, the Company also entered into a sponsored research agreement dated June 30, 2022 with CHMC for research related to the CHMC Agreement (the “CHMC SRA”). Pursuant to this research agreement, the Company is obligated to pay CHMC an aggregate amount not-to-exceed \$247,705. The CHMC SRA has a term of one year, and is cancelable upon 60 days written notice by either party for convenience. In addition, either party may terminate the CHMC SRA in the event the other party (a) files or has filed against it a petition under the Bankruptcy Act (among other things) or (b) fails to perform or otherwise breaches its obligations under the agreement, and has not cured such failure or breach within 30 days of notice of material breach.

During the three and nine months ended September 30, 2022, the Company incurred related research and development expenses of approximately \$37,000, which was included in accrued expenses at September 30, 2022. There were no such expenses incurred during the three and nine months ended September 30, 2021.

Oxford University Innovation Limited Agreement

On July 16, 2019, we entered into an exclusive, worldwide license agreement with Oxford University Innovation Limited, which we refer to as the OUI Agreement, pursuant to which we obtained the right to develop and commercialize certain licensed technology entitled “Immunogenic Composition.”

Under the OUI Agreement, we agreed to fund three years’ worth of salaries for Dr. Craig Thompson in the University’ Department of Zoology through a sponsored research agreement with Oxford University, as well as royalties on all net sales of licensed products, along with certain development and milestone payments (among others). For additional details regarding our relationship with OUI, see Note 5 to our financial statements included elsewhere in this Report. The OUI license includes the following patents:

U.S. Patent Application No.	U.S. Patent No.	Granted Claim Type	U.S. Expiration	Foreign Counterparts
16/326,749	11,123,422	Compositions and method of treatment	8/25/2037	Pending applications in Australia, Canada, China, EU and Japan
17/458,712	pending	pending	[8/25/2037]*	

* Projected expiration if patent issues: 20 years from earliest non-provisional application filing date.

** This is a pending application. Claim type will be determined after U.S. prosecution is complete. The claim type sought includes compositions of the compositions and method of treatment.

St. Jude Children’s Research Hospital, Inc. Agreement

On January 27, 2020, we entered into an exclusive, worldwide license agreement with St. Jude Children’s Research Hospital, Inc., as amended, which we refer to as the St. Jude Agreement, pursuant to which we acquired the right to develop certain licensed products and produce vaccines for use in humans.

Under the St. Jude Agreement, we agreed to pay an initial license fee, an annual maintenance fee, milestone payments, patent reimbursement, and running royalties based on the net sales of licensed products. On May 11, 2022, the Company and St. Jude entered into a first amendment to the St. Jude Agreement (the “St. Jude Amendment”). The St. Jude Amendment provides for a revised development milestone timeline, a one-time license fee of \$5,000, and an increase to the royalty rate from 4% to 5%. The St. Jude Amendment also provides for an increase to the contingent milestone payments, from \$1.0 million to \$1.9 million in the aggregate; specifically, development milestones of \$0.3 million, regulatory milestones of \$0.6 million, and commercial milestones of \$1.0 million. For additional details regarding our relationship with St. Jude, see Notes 5 and 7 to our financial statements included elsewhere in this Report. The St. Jude license includes the following patents:

U.S. Patent Application No.	U.S. Patent No.	Granted Claim Type	U.S. Expiration	Foreign Counterparts
14/345,988	9,265,819	Compositions and method of treatment	9/19/2032	none
17/602,414 [#]	pending	pending	[3/12/2040]*	Pending Applications in: Australia, Brazil, Canada, China, Europe, Hong Kong, Japan and Korea

* Projected expiration if patent issues: 20 years from earliest non-provisional application filing date.

U.S. National stage entry of WO 2020/183420 (PCT/IB2020/052250).

** This is a pending application. Claim type will be determined after U.S. prosecution is complete. The claim type sought includes compositions of the compositions and method of treatment.

St. Jude Children's Sponsored Research Agreement

In addition to the St. Jude Agreement, the Company also entered into a sponsored research agreement dated May 3, 2021 with St. Jude for research related to the St. Jude Agreement (the "St. Jude SRA"). Pursuant to the St. Jude SRA, the Company is obligated to pay St. Jude an aggregate amount of \$73,073 in two parts, Phase I for \$57,624 and Phase II for \$15,449. This sponsored research project began during 2021, and the Company recorded approximately \$8,000 in related accrued expenses at December 31, 2021.

The Company entered into a second sponsored research agreement with St. Jude, dated August 29, 2022, pursuant to which the Company is obligated to pay St. Jude an amount of \$75,603 which is due within 30 days of the effective date of the agreement.

During the three and nine months ended September 30, 2022, the Company incurred related research and development expenses related to the sponsored research agreements with St. Jude of approximately \$8,000 and \$15,000, respectively, and had approximately \$8,000 recorded in accrued expenses at September 30, 2022. During the three and nine months ended September 30, 2021, the Company incurred related research and development expenses of approximately \$0 and \$58,000, respectively.

COVID-19 Impacts

Our business, results of operations and financial condition have been and may continue to be impacted by the COVID-19 pandemic and could be further impacted by supply chain interruptions, extended "shelter-in-place" orders or advisories, facility closures or other reasons related to the pandemic. As of the date of this Quarterly Report on Form 10-Q, the extent to which COVID-19 could materially impact our financial conditions, liquidity or results of operations is uncertain.

To the extent COVID-19 disruptions continue to adversely impact our business, results of operations and financial condition, it may also have the effect of heightening risks relating to our ability to successfully commercialize newly developed or acquired products, consolidation in the healthcare industry, and maintenance of our contractual relationships.

Components of Results of Operations

Research and Development Expenses

Substantially all of our research and development expenses consist of expenses incurred in connection with the development of our product candidates. These expenses include fees paid to third parties to conduct certain research and development activities on our behalf, consulting costs, costs for laboratory supplies, product acquisition and license costs, certain payroll and personnel-related expenses, including salaries and bonuses, employee benefit costs and stock-based compensation expenses for our research and product development employees and allocated overheads, including information technology costs and utilities. We expense both internal and external research and development expenses as they are incurred.

We do not allocate our costs by product candidate, as a significant amount of research and development expenses include internal costs, such as payroll and other personnel expenses, laboratory supplies and allocated overhead, and external costs, such as fees paid to third parties to conduct research and development activities on our behalf, are not tracked by product candidate.

We expect our research and development expenses to increase substantially for at least the next few years, as we seek to initiate additional clinical trials for our product candidates, complete our clinical programs, pursue regulatory approval of our product candidates and prepare for the possible commercialization of such product candidates. Predicting the timing or cost to complete our clinical programs or validation of our commercial manufacturing and supply processes is difficult and delays may occur because of many factors, including factors outside of our control. For example, if the FDA or other regulatory authorities were to require us to conduct clinical trials beyond those that we currently anticipate, we could be required to expend significant additional financial resources and time on the completion of clinical development. Furthermore, we are unable to predict when or if our product candidates will receive regulatory approval with any certainty.

General and Administrative Expenses

General and administrative expenses consist principally of payroll and personnel expenses, including salaries and bonuses, benefits and stock-based compensation expenses, professional fees for legal, consulting, accounting and tax services, including information technology costs, and other general operating expenses not otherwise classified as research and development expenses.

We anticipate that our general and administrative expenses will continue to increase when compared to historical levels, as a result of increased personnel costs, expanded infrastructure and higher consulting, legal and accounting services costs associated with complying with the applicable stock exchange and the SEC requirements, investor relations costs and director and officer insurance premiums associated with being a public company.

Results of Operations

Comparison of the Three Months Ended September 30, 2022 and 2021

The following table summarizes our statements of operations for the periods indicated:

	Three Months Ended September 30, 2022	Three Months Ended September 30, 2021	\$ Change	% Change
Operating expenses				
General and administrative	\$ 2,694,254	\$ 825,999	\$ 1,868,255	226.2%
Research and development	1,175,480	269,925	905,555	335.5%
Total operating expenses	<u>3,869,734</u>	<u>1,095,924</u>	<u>2,773,810</u>	<u>253.1%</u>
Loss from operations	<u>(3,869,734)</u>	<u>(1,095,924)</u>	<u>(2,773,810)</u>	<u>253.1%</u>
Total other income	<u>(3,072)</u>	<u>—</u>	<u>(3,072)</u>	<u>*</u>
Net loss	<u>\$ (3,866,662)</u>	<u>\$ (1,095,924)</u>	<u>\$ (2,770,738)</u>	<u>252.8%</u>

* Not meaningful

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, of approximately \$0.2 million, an increase in audit, accounting, and legal services of approximately \$0.1 million, increases in various business activities related to company growth and development such as entering into a new lease, travel, patent-related expenses, and business advisory services totaling approximately \$0.4 million, an expense associated with the accrued loss contingency related to Boustead of \$0.8 million, and increases in other business activities related to now being a public company of approximately \$0.4 million.

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, of approximately \$0.2 million and an increase in preclinical development activities of approximately \$0.7 million, related primarily to BWV-201.

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.

Comparison of the Nine Months Ended September 30, 2022 and 2021

The following table summarizes our statements of operations for the periods indicated:

	Nine Months Ended September 30, 2022	Nine Months Ended September 30, 2021	\$ Change	% Change
Operating expenses				
General and administrative	\$ 7,311,243	\$ 1,326,275	\$ 5,984,968	451.3%
Research and development	2,924,037	887,704	2,036,333	229.4%
Total operating expenses	<u>10,235,280</u>	<u>2,213,979</u>	<u>8,021,301</u>	<u>362.3%</u>
Loss from operations	(10,235,280)	(2,213,979)	(8,021,301)	362.3%
Total other income	(33,375)	—	(33,375)	*
Net loss	<u>\$ (10,201,905)</u>	<u>\$ (2,213,979)</u>	<u>\$ (7,987,926)</u>	<u>360.8%</u>

* Not meaningful

General and Administrative Expenses

For the nine months ended September 30, 2022, general and administrative expenses increased by \$6.0 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, of approximately \$2.1 million, an increase in audit, accounting, and legal services of approximately \$0.6 million, increases in various business activities related to company growth and development such as entering into a new lease, patent-related expenses, travel, and business advisory services totaling approximately \$0.8 million, an expense associated with the accrued loss contingency related to Boustead of \$1.3 million, and increases in other business activities related to now being a public company of approximately \$0.9 million. In addition, during the nine months ended September 30, 2022, the Company incurred approximately \$0.3 million for a non-recurring termination penalty to the Company's former underwriter, for early termination of the agreement with that underwriter.

Research and Development Expenses

For the nine months ended September 30, 2022, research and development expenses increased by approximately \$2.0 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, of approximately \$0.8 million, increase in preclinical development activities of approximately \$1.3 million mainly related to BWV-201, and an increase in external research and development personnel costs of approximately \$0.3 million, offset by a decrease in license fees of approximately \$0.4 million, primarily related to the one-time license fees incurred pursuant to the CHMC Agreement during the nine months ended September 30, 2021.

Other Income

Other income relates to the change in fair value of the contingent warrant liability, which was incurred at the close of the April and August private placements during the nine months ended September 30, 2022. There was no other income or expense during the nine months ended September 30, 2021.

Liquidity and Capital Resources

Liquidity and Capital Resources

Since inception, we have devoted substantially all of our efforts to research and development, undertaking preclinical studies and enabling manufacturing activities in support of our product development efforts, hiring personnel, acquiring and developing our technology and vaccine candidates, organizing and staffing our company, performing business planning, establishing our intellectual property portfolio and raising capital to support and expand such activities. We do not have any products approved for sale and have not generated any revenue from product sales. We have incurred net losses in each year since inception and expect to continue to incur net losses in the foreseeable future. Our net loss was approximately \$3.9 million and \$10.2 million for the three and nine months ended September 30, 2022, respectively. As of September 30, 2022, we had an accumulated deficit of approximately \$16.2 million. We also generated negative operating cash flows of approximately \$5.9 million for the nine months ended September 30, 2022.

On February 23, 2022, we completed our IPO in which we received approximately \$17.1 million in net proceeds, after deducting the underwriting discount, and offering expenses. In addition, on April 19, 2022, we completed the April Private Placement in which we received approximately \$6.9 million in net cash proceeds, after deducting placement agent fees and other offering expenses. Further, on August 11, 2022, the Company completed the August Private Placement in which it received approximately \$8.7 million in net proceeds, after deducting placement agent fees and other offering expenses. The Company believes the existing cash at September 30, 2022, will be sufficient to continue operations, satisfy its obligations and fund the future expenditures that will be required to conduct the clinical and regulatory work to develop its product candidates for at least one year after the date that the accompanying condensed financial statements were issued.

However, we will require significant amounts of additional capital to continue to fund our operations in the long term and complete our research and development activities. We will continue seeking additional financing sources to meet our working capital requirements, make continued investment in research and development and make capital expenditures needed for us to maintain and expand our business. We may not be able to obtain additional financing on terms favorable to us, if at all. If we are unable to obtain adequate financing or financing on terms satisfactory to us when we require it, or if we expend capital on projects that are not successful, our ability to continue to support our business growth and to respond to business challenges could be significantly limited, or we may even have to cease our operations. If we raise additional funds through further issuances of equity or convertible debt securities, our existing stockholders could suffer significant dilution, and any new equity securities we issue could have rights, preferences and privileges superior to those of holders of our common stock.

Future Funding Requirements

Our primary uses of cash are to fund our operations, which consist primarily of research and development expenditures related to our programs and general and administrative expenditures. We anticipate that we will continue to incur significant expenses for the foreseeable future as we continue to advance our vaccine candidates, expand our corporate infrastructure, including the costs associated with being a public company and further our research and development initiatives for our vaccine candidates. We are subject to all of the risks typically related to the development of new drug candidates, and we may encounter unforeseen expenses, difficulties, complications, delays and other unknown factors that may adversely affect our business. We anticipate that we will need substantial additional funding in connection with our continuing operations in order to execute our long-term business plan.

We estimate that, based on our existing cash as of September 30, 2022, we have cash on hand sufficient to fund our operations for at least the next 12 months. We will need to raise additional capital prior to commencing additional pivotal trials for certain of our vaccine candidates. Until we can generate a sufficient amount of revenue from the commercialization of our vaccine candidates or from collaboration agreements with third parties, if ever, we expect to finance our future cash needs through public or private equity or debt financings, third-party (including government) funding and marketing and distribution arrangements, as well as other collaborations, strategic alliances and licensing arrangements, or any combination of these approaches. The future sale of equity or convertible debt securities may result in dilution to our stockholders and, in the case of preferred equity securities or convertible debt, those securities could provide for rights, preferences or privileges senior to those of our common stock. Debt financings may subject us to covenant limitations or restrictions on our ability to take specific actions, such as incurring additional debt, making capital expenditures or declaring dividends. Our ability to raise additional funds may be adversely impacted by deteriorating global economic conditions and the recent disruptions to and volatility in the credit and financial markets in the United States and worldwide resulting from the ongoing COVID-19 pandemic. There can be no assurance that we will be successful in acquiring additional funding at levels sufficient to fund our operations or on terms favorable or acceptable to us. If we are unable to obtain adequate financing when needed or on terms favorable or acceptable to us, we may be forced to delay, reduce the scope of or eliminate one or more of our research and development programs.

Our future capital requirements will depend on many factors, including:

- the timing, scope, progress, results and costs of research and development, testing, screening, manufacturing, preclinical and non-clinical studies and clinical trials, including any impacts related to the COVID-19 pandemic;
- the outcome, timing and cost of seeking and obtaining regulatory approvals from the FDA and comparable foreign regulatory authorities, including the potential for such authorities to require that we perform field efficacy studies for our vaccine candidates, require more studies than those that we currently expect or change their requirements regarding the data required to support a marketing application;
- the cost of building a sales force in anticipation of any product commercialization;
- the costs of future commercialization activities, including product manufacturing, marketing, sales, royalties and distribution, for any of our vaccine candidates for which we receive marketing approval;
- our ability to maintain existing, and establish new, strategic collaborations, licensing or other arrangements and the financial terms of any such agreements, including the timing and amount of any future milestone, royalty or other payments due under any such agreement;
- any product liability or other lawsuits related to our products;
- the expenses needed to attract, hire and retain skilled personnel;
- the revenue, if any, received from commercial sales, or sales to foreign governments, of our vaccine candidates for which we may receive marketing approval;
- the costs to establish, maintain, expand, enforce and defend the scope of our intellectual property portfolio, including the amount and timing of any payments we may be required to make, or that we may receive, in connection with licensing, preparing, filing, prosecuting, defending and enforcing our patents or other intellectual property rights;
- expenses needed to attract, hire and retain skilled personnel;
- the costs of operating as a public company; and
- the impact of the COVID-19 pandemic, which may exacerbate the magnitude of the factors discussed above.

A change in the outcome of any of these or other variables could significantly change the costs and timing associated with the development of our vaccine candidates. Furthermore, our operating plans may change in the future, and we may need additional funds to meet operational needs and capital requirements associated with such change.

Cash Flows

The following table summarizes our cash flows for the periods indicated:

	Nine Months Ended September 30, 2022	Nine Months Ended September 30, 2021
Net cash used in operating activities	(5,897,641)	(1,369,831)
Net cash used in investing activities	(9,339)	—
Net cash provided by (used in) financing activities	33,115,222	(196,975)
Net increase (decrease) in cash	27,208,242	(1,566,806)

Cash Flows from Operating Activities

Net cash used in operating activities for the nine months ended September 30, 2022 was approximately \$5.9 million, which primarily resulted from a net loss of approximately \$10.2 million, which was partially offset by noncash stock-based compensation of approximately \$1.8 million, and a net change in our operating assets and liabilities of approximately \$2.5 million.

Net cash used in operating activities for the nine months ended September 30, 2021 was approximately \$1.4 million, which primarily resulted from a net loss of approximately \$2.2 million, and was partially offset by noncash stock-based compensation of approximately \$0.1 million and a net change in our operating assets and liabilities of approximately \$0.7 million.

Cash Flows from Investing Activities

Net cash used in investing activities for the nine months ended September 30, 2022 was \$9,000, which resulted from purchases of property and equipment. There were no such purchases, or other investing activities during the nine months ended September 30, 2021.

Cash Flows from Financing Activities

Net cash provided by financing activities for the nine months ended September 30, 2022 was approximately \$33.1 million, and resulted primarily from the close of our IPO and the April and August Private Placements. No financing activities took place during the nine months ended September 30, 2021.

Legal Contingencies

From time to time, we may become involved in legal proceedings arising from the ordinary course of business. We record a liability for such matters when it is probable that future losses will be incurred and that such losses can be reasonably estimated.

Off-Balance Sheet Arrangements

During the periods presented we did not have, nor do we currently have, any off-balance sheet arrangements as defined in the rules and regulations of the SEC.

Recent Accounting Pronouncements Not Yet Adopted

See Note 3 to our financial statements included elsewhere in this Report for more information.

Critical Accounting Policies and Estimates

Our financial statements have been prepared in accordance with U.S. generally accepted accounting principles (“U.S. GAAP”). The preparation of these financial statements requires us to make estimates and judgments that affect the reported amounts of assets, liabilities, and expenses and the disclosure of contingent assets and liabilities in our financial statements. On an ongoing basis, we evaluate our estimates and judgments, including those related to accrued research and development expenses, fair value of common stock, judgments used in the evaluation of potential loss contingencies, and stock-based compensation. We base our estimates on historical experience, known trends and events and various other factors that are believed to be reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources. Actual results may differ from these estimates under different assumptions or conditions.

While our significant accounting policies are described in more detail in Note 3 to our financial statements included elsewhere in this Report, we believe the following accounting policies and estimates to be most critical to the judgments and estimates used in the preparation of our financial statements.

Accrued Research and Development Expenses

We have entered into various agreements with contract manufacturing organizations, or CMOs, and may enter into contracts with clinical research organizations, or CROs, in the future. As part of the process of preparing our financial statements, we are required to estimate our accrued research and development expenses as of each balance sheet date. This process involves reviewing open contracts and purchase orders, communicating with our personnel and third parties to identify services that have been performed on our behalf and estimating the level of service performed and the associated cost incurred for the service when we have not yet been invoiced or otherwise notified of the actual cost. We make estimates of our accrued research and development expenses as of each balance sheet date based on facts and circumstances known to us at that time. We periodically confirm the accuracy of our estimates with the service providers and make adjustments, if necessary. The significant estimates in our accrued research and development expenses include the costs incurred for services performed by our vendors in connection with research and development activities for which we have not yet been invoiced.

We accrue for costs related to research and development activities based on our estimates of the services received and efforts expended pursuant to quotes and contracts with vendors, including CMOs, that conduct research and development on our behalf. The financial terms of these agreements are subject to negotiation, vary from contract to contract and may result in uneven payment flows. There may be instances in which payments made to our vendors will exceed the level of services provided and result in a prepayment of the research and development expense. Advance payments for goods and services that will be used in future research and development activities are expensed when the activity has been performed or when the goods have been received. We make significant judgments and estimates in determining accrued research and development liabilities as of each reporting period based on the estimated time period over which services will be performed and the level of effort to be expended. If the actual timing of the performance of services or the level of effort varies from our estimate, we adjust the accrual or prepaid expense accordingly.

Although we do not expect our estimates to be materially different from amounts actually incurred, if our estimates of the status and timing of services performed differ from the actual status and timing of services performed, it could result in us reporting amounts that are too high or too low in any particular period. To date, there have been no material differences between our estimates of such expenses and the amounts actually incurred.

Contingencies

Accruals are recorded for loss contingencies when it is probable that a liability has been incurred and the amount of the related loss can be reasonably estimated. The Company evaluates, on a quarterly basis, developments in legal proceedings and other matters that could cause an increase or decrease in the amount of the liability that has been accrued previously. Considering facts known at the time of the assessment, the Company determines whether potential losses are considered reasonably possible or probable and whether they are estimable. Based upon this assessment, the Company carries out an evaluation of disclosure requirements and considers possible accruals in the financial statements.

Warrants

The Company determines the accounting classification of warrants that are issued, as either liability or equity, by first assessing whether the warrants meet liability classification in accordance with ASC 480-10, Accounting for Certain Financial Instruments with Characteristics of both Liabilities and Equity, (“ASC 480-10”), and then in accordance with ASC 815-40, Derivatives and Hedging - Contracts in Entity’s Own Equity (“ASC 815-40”). Under ASC 480-10, warrants are considered liability-classified if the warrants are mandatorily redeemable, obligate the issuer to settle the warrants or the underlying shares by paying cash or other assets, or must or may require settlement by issuing variable number of shares.

If the warrants do not meet liability classification under ASC 480-10, the Company assesses the requirements under ASC 815-40, which states that contracts that require or may require the issuer to settle the contract for cash are liabilities recorded at fair value, irrespective of the likelihood of the transaction occurring that triggers the net cash settlement feature. If the warrants do not require liability classification under ASC 815-40, in order to conclude equity classification, the Company assesses whether the warrants are indexed to its common stock and whether the warrants are classified as equity under ASC 815-40 or other applicable GAAP. After all relevant assessments are made, the Company concludes whether the warrants are classified as liability or equity. Liability-classified warrants are required to be accounted for at fair value both on the date of issuance and on subsequent accounting period ending dates, with all changes in fair value after the issuance date recorded as a component of other income (expense), net in the statements of operations. Equity-classified warrants are accounted for at fair value on the issuance date with no changes in fair value recognized after the issuance date.

Stock-Based Compensation

The Company expensed stock-based compensation to employees and non-employees over the requisite service period based on the estimated grant-date fair value of the awards. Stock-based awards to employees with graded-vesting schedules are recognized, using the accelerated attribution method, on a straight-line basis over the requisite service period for each separately vesting portion of the award.

The Company estimates the fair value of stock option grants using the Black-Scholes option pricing model and the assumptions used in calculating the fair value of stock-based awards represent management's best estimates and involve inherent uncertainties and the application of management's judgment.

Expected Term — The expected term of options represents the period that the Company's stock-based awards are expected to be outstanding based on the simplified method, which is the half-life from vesting to the end of its contractual term.

Expected Volatility — Volatility is a measure of the amount by which the Company's share price has historically fluctuated or is expected to fluctuate (i.e., expected volatility) during a period. Due to the lack of an adequate history of a public market for the trading of the Company's common stock and a lack of adequate company-specific historical and implied volatility data, the Company computes stock price volatility over expected terms based on comparable companies' historical common stock trading prices. For these analyses, the Company has selected companies with comparable characteristics, including enterprise value, risk profiles, and position within the industry.

Common Stock Fair Value — Due to the absence of an active market for the Company's common stock prior to the IPO, the fair value of the common stock underlying the Company's stock options granted prior to the IPO was estimated at each grant date and was determined with the assistance of an independent third-party valuation expert. The assumptions underlying these valuations represented management's best estimates, which involved inherent uncertainties and the application of significant levels of management judgment. After the completion of the IPO, the fair value of each share of common stock is based on the closing price of the Company's common stock as reported by the Nasdaq Capital Market.

Risk-Free Interest Rate — The Company bases the risk-free interest rate on the implied yield available on U.S. Treasury securities with a remaining term commensurate with the estimated expected term.

Expected Dividend — The Company has never declared or paid any cash dividends on its shares of common stock and does not plan to pay cash dividends in the foreseeable future, and, therefore, uses an expected dividend yield of zero in its valuation models.

The Company recognizes forfeitures of equity awards as they occur.

Fair value of common stock

In order to determine the fair value of shares of common stock of the Company when issuing stock options prior to the IPO, and computing their estimated stock-based compensation expense, its board of directors considered with input from third party valuations, among other things, contemporaneous valuations of the Company's common stock. Given the absence of a public trading market of the Company's capital stock prior to the IPO, its board of directors has exercised reasonable judgment and considered a number of objective and subjective factors to determine the best estimate of the fair value of our common and preferred stock, including:

- the prices, rights, preferences and privileges of our preferred stock relative to our common stock;
- our business, financial condition and results of operations, including related industry trends affecting our operations;

- the likelihood of achieving a liquidity event, such as an initial public offering, or IPO, or sale of our company, given prevailing market conditions;
- the lack of marketability of our common stock;
- the market performance of comparable publicly traded companies;
- U.S. and global economic and capital market conditions and outlook; and
- Common stock valuation methodology.

In estimating the fair market value of common stock of the Company, its board of directors first determined the equity value of its business using accepted valuation methods.

The Company engaged a third party valuation specialist to conduct a valuation, which used its recent preferred stock financing as a starting point and determined the equity value of the company based on the Backsolve method using an Option Pricing Method (OPM) to calculate the implied value based on a market approach. The Company's equity value was allocated using OPM to estimate the fair market value of the Company's classes of equity.

After the completion of the IPO, the fair value of each share of common stock is based on the closing price of the Company's common stock as reported by the Nasdaq Capital Market.

Quantitative and Qualitative Disclosures About Market Risk

We are a smaller reporting company as defined by Rule 12b-2 of the Exchange Act and are not required to provide the information otherwise required under this item.

JOBS Act

Section 107 of the JOBS Act also provides that an "emerging growth company" can take advantage of the extended transition period provided in Section 7(a)(2)(B) of the Securities Act for complying with new or revised accounting standards. In other words, an "emerging growth company" can delay the adoption of new or revised accounting standards until those standards would otherwise apply to private companies. We have elected to avail ourselves of this extended transition period.

For as long as we remain an "emerging growth company" under the recently enacted JOBS Act, we will, among other things:

- be exempt from the provisions of Section 404(b) of the Sarbanes-Oxley Act, which requires that our independent registered public accounting firm provide an attestation report on the effectiveness of our internal control over financial reporting;
- be permitted to omit the detailed compensation discussion and analysis from proxy statements and reports filed under the Exchange Act and instead provide a reduced level of disclosure concerning executive compensation; and
- be exempt from any rules that may be adopted by the Public Company Accounting Oversight Board requiring mandatory audit firm rotation or a supplement to the auditor's report on the financial statements.

Although we are still evaluating the JOBS Act, we currently intend to take advantage of some or all of the reduced regulatory and reporting requirements that will be available to us so long as we qualify as an "emerging growth company," including the extension of time to comply with new or revised financial accounting standards available under Section 102(b) of the JOBS Act. Among other things, this means that our independent registered public accounting firm will not be required to provide an attestation report on the effectiveness of our internal control over financial reporting so long as we qualify as an emerging growth company, which may increase the risk that weaknesses or deficiencies in our internal control over financial reporting go undetected. Likewise, so long as we qualify as an emerging growth company, we may elect not to provide you with certain information, including certain financial information and certain information regarding compensation of our executive officers, that we would otherwise have been required to provide in filings we make with the SEC, which may make it more difficult for investors and securities analysts to evaluate our company. As a result, investor confidence in our company and the market price of our common stock may be materially and adversely affected.

Related Party Transactions during the three and nine months ended September 30, 2022

Stock Options

On May 4, 2022 and August 22, 2022, the Company's compensation committee approved stock option grants under the Company's 2022 Equity Incentive Plan to certain of the Company's executive officers and board members. The stock options granted on May 4, 2022 totaled 694,540 options, of which 500,000 were granted to the Company's executive officers, and all of which have an exercise price of \$6.45. The stock options granted on August 22, 2022 totaled 4,073 options, which have an exercise price of \$3.48.

One-Time Bonuses

Joe Hernandez, Chairman and CEO

On May 6, 2022, the Company's compensation committee approved a one-time bonus award of \$140,000 to Mr. Hernandez in recognition of Mr. Hernandez's efforts in connection with the Company's IPO.

Erin Henderson, Chief Business Officer and Secretary

On April 4, 2022, the Company's compensation committee approved a one-time bonus award of \$100,000 to Ms. Henderson in recognition of Ms. Henderson's efforts in connection with the Company's IPO.

Boustead Demand Letter and Settlement Agreement and Release

On April 15, 2022, the Company received a demand letter (the "Demand Letter") from Boustead Securities, LLC ("Boustead"). The Demand Letter alleged that the Company breached the Underwriting Agreement entered into between Boustead and the Company, dated February 17, 2022, in connection with the Company's initial public offering. The Demand Letter alleged that, by engaging Wainwright as placement agent in the April Private Placement, the Company breached Boustead's right of first refusal ("ROFR") to act as placement agent granted to Boustead under the Underwriting Agreement and, as a result of selling securities in the April Private Placement, breached the Company's obligation under the Underwriting Agreement not to offer, sell, issue, agree or contract to sell or issue or grant or modify the terms of any option for the sale of, any securities prior to February 17, 2023 (the "Standstill").

On October 9, 2022, the Company and Boustead entered into a Settlement Agreement and Release (the "Settlement Agreement"), pursuant to which Boustead agreed to waive the ROFR and the Standstill, and to release the Company from certain claims with respect to the April Private Placement, the August Private Placement, and all future private, public equity or debt offerings of the Company. As consideration for such waiver and termination of the Underwriting Agreement, the Company agreed to pay Boustead a cash fee of \$1,000,000, \$50,000 in legal expenses, and release Boustead from all claims, subject to certain exceptions. In addition, the Company agreed to issue to Boustead 93,466 shares of restricted common stock in exchange for the cancellation of 111,111 warrants issued to Boustead in connection with the initial public offering. Concurrent with the execution of the Settlement Agreement, the Company and Boustead Capital Markets, LLP ("Boustead Capital") entered into a three-month Advisory Agreement (the "Advisory Agreement") for which consideration equal to 200,000 shares of restricted common stock, with no vesting provisions, was issuable to Boustead Capital upon execution of the Advisory Agreement.

The Company recognized approximately \$1.3 million as an accrued loss contingency in the accompanying condensed balance sheet as of September 30, 2022.

Appointment of New Board Member, Compensation Committee Member, and Nominating and Corporate Governance Committee Member

On November 4, 2022, the Company's Board of Directors (the "Board") appointed a new Class I Director to replace a director who resigned from the Board on the same day. The new Class I Director was also appointed to the Compensation Committee of the Board and the Nomination and Corporate Governance Committee of the Board. On November 8, 2022, the Board granted 3,610 stock options to the new Class I Director, with an exercise price of \$1.06.

Buyback Program

On November 10, 2022, the Board approved a share repurchase program to allow for the Company to repurchase up to 5 million shares, with a maximum price of \$1.00 per share, with discretion to management to make purchases subject to market conditions.

Item 3. Quantitative and Qualitative Disclosures About Market Risk

As a smaller reporting company, we are not required to provide the information required by this item.

Item 4. Controls and Procedures.

Evaluation of Disclosure Controls and Procedures

The Sarbanes-Oxley Act requires, among other things, that we maintain effective disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e)) that are designed to ensure that information required to be disclosed by us in reports we file or submit under the Securities Exchange Act of 1934, as amended, is recorded, processed, summarized and reported within the appropriate time periods, and that such information is accumulated and communicated to the Chief Executive Officer and Chief Financial Officer, as appropriate, to allow timely discussions regarding required disclosure. We, under the supervision of and with the participation of our management, including our Chief Executive Officer and Chief Financial Officer, have evaluated the effectiveness of our disclosure controls and procedures as of September 30, 2022. Based on that evaluation, our Chief Executive Officer and Chief Financial Officer concluded that the design and operation of our disclosure controls and procedures were not effective because of material weaknesses in our internal control over financial reporting, which are further described below in *Material Weaknesses in Internal Control Over Financial Reporting*.

Material Weaknesses in Internal Control Over Financial Reporting

A material weakness is a deficiency, or a combination of deficiencies, in internal control over financial reporting, such that there is a reasonable possibility that a material misstatement of our annual or interim financial statements will not be prevented or detected on a timely basis. The material weaknesses identified as of September 30, 2022 are as follows:

- We failed to employ a sufficient number of staff to maintain optimal segregation of duties and to provide optimal levels of oversight in order to process financial information in a timely manner, analyze and account for complex, non-routine transactions, and prepare financial statements.
- We do not yet have adequate internal controls in place for the timely identification, approval or reporting of related party transactions.

The above material weaknesses did not result in a material misstatement of our previously issued financial statements, however, it could result in a misstatement of our account balances or disclosures that would result in a material misstatement of our annual or interim financial statements that would not be prevented or detected. We have developed a remediation plan for these material weaknesses which is described below in *Remediation of Material Weaknesses*.

Remediation of Material Weaknesses

We are committed to maintaining a strong internal control environment and implementing measures designed to help ensure that the material weaknesses are remediated as soon as possible. We believe we have made progress towards remediation and continue to implement our remediation plan for the material weaknesses, which includes steps to increase dedicated qualified personnel including financial consultants, improve reporting processes, and design and implement new controls. We have also designed a related party transactions approval policy which our Board of Directors approved on June 24, 2022. Further, we have designed certain controls surrounding the identification, approval and reporting of related party transactions, that we expect to implement by the end of 2022. We will consider the material weaknesses remediated after the applicable controls operate for a sufficient period of time, and management has concluded, through testing, that the controls are operating effectively.

The process of designing and implementing an effective accounting and financial reporting system is a continuous effort that requires us to anticipate and react to changes in our business and the economic and regulatory environments and to expend significant resources to maintain an accounting and financial reporting system that is adequate to satisfy our reporting obligations. As we continue to evaluate and take actions to improve our internal control over financial reporting, we may determine to take additional actions to address control deficiencies or determine to modify certain of the remediation measures described above. We cannot assure you that the measures we have taken to date, or any measures we may take in the future, will be sufficient to remediate the material weakness we have identified or avoid potential future material weaknesses.

Inherent Limitation on the Effectiveness of Internal Control Processes

Our management, including our Chief Executive Officer and Chief Financial Officer, does not expect that our disclosure controls or our internal control over financial reporting will prevent all errors and all fraud. A control system, no matter how well designed and operated, can provide only reasonable, not absolute, assurance that the objectives of the control system are met. Because of the inherent limitations in all control systems, no evaluation of controls can provide absolute assurance that all control issues and instances of fraud, if any, have been detected. These inherent limitations include the realities that judgments in decision-making can be faulty, and that breakdowns can occur because of a simple error or mistake. Additionally, controls can be circumvented by the individual acts of some persons, by collusion of two or more people or by management override of the controls. The design of any system of controls is also based in part upon certain assumptions about the likelihood of future events, and there can be no assurance that any design will succeed in achieving its stated goals under all potential future conditions; over time, controls may become inadequate because of changes in conditions, or the degree of compliance with policies or procedures may deteriorate. Because of the inherent limitations in a cost-effective control system, misstatements due to error or fraud may occur and not be detected.

Changes in Internal Control over Financial Reporting

During the fiscal quarter ended September 30, 2022, there were no changes in our internal control over financial reporting (as such term is defined in Rules 13a-15(f) and 15d-15(f) of the Exchange Act) that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

PART II – OTHER INFORMATION

Item 1. Legal Proceedings

We are not currently subject to any material legal proceedings, nor, to our knowledge, is any material legal proceeding threatened against us or any of our officers or directors in their corporate capacity.

Item 1A. Risk Factors

For the complete list of risks relating to our operations, see the section titled “Risk Factors” contained in our Registration Statement on Form S-1, filed with the SEC on August 29, 2022. Any of these factors could result in a significant or material adverse effect on our results of operations or financial condition. Additional risk factors not presently known to us or that we currently deem immaterial may also impair our business or results of operations.

Item 2. Unregistered Sales of Equity Securities and Use of Proceeds

There are no transactions that have not been previously included in a Current Report on Form 8-K, aside from the following. As discussed above, on October 9, 2022, the Company and Boustead entered into a Settlement Agreement pursuant to which Boustead agreed to waive certain obligations of the Company under the Underwriting Agreement that was entered into between the two parties in connection with the Company’s IPO in February 2022. Pursuant to this agreement, the Company agreed to issue to Boustead 93,466 shares of restricted common stock in exchange for the cancellation of 111,111 warrants issued to Boustead in connection with the IPO. In addition, the Company and Boustead Capital also entered into the Advisory Agreement for which consideration equal to 200,000 shares of restricted common stock, with no vesting provisions, was issuable to Boustead Capital upon execution of the Advisory Agreement.

Item 3. Default Upon Senior Securities

None.

Item 4. Mine Safety Disclosures

Not applicable.

Item 5. Other Information

None.

Item 6. Exhibits.

The following documents are filed as exhibits to this Quarterly Report on Form 10-Q.

EXHIBIT INDEX

Exhibit Number	Description of Document
10.1	Form of Securities Purchase Agreement, dated as of August 9, 2022, by and among the Registrant and the Purchasers (Incorporated by reference to the Registrant's Current Report on Form 8-K, filed with the SEC on August 11, 2022).
10.2	Form of Registration Rights Agreement, dated as of August 9, 2022, by and among the Registrant and the Purchasers (Incorporated by reference to the Registrant's Current Report on Form 8-K, filed with the SEC on August 11, 2022).
10.3*	Settlement Agreement and Release, dated October 9, 2022, by and between the Registrant and Boustead Securities, LLC.
31.1**	Certification of Principal Executive Officer Pursuant to Securities Exchange Act Rules 13a-14(a) and 15(d)-14(a), as adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002
31.2**	Certification of Principal Financial Officer Pursuant to Securities Exchange Act Rules 13a-14(a) and 15(d)-14(a), as adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002
32.1**	Certification of Principal Executive Officer Pursuant to 18 U.S.C. Section 1350, as adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002
32.2**	Certification of Principal Financial Officer Pursuant to 18 U.S.C. Section 1350, as adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002
101.INS**	Inline XBRL Instance Document.
101.SCH**	Inline XBRL Taxonomy Extension Schema Document.
101.CAL**	Inline XBRL Taxonomy Extension Calculation Linkbase Document.
101.DEF**	Inline XBRL Taxonomy Extension Definition Linkbase Document.
101.LAB**	Inline XBRL Taxonomy Extension Label Linkbase Document.
101.PRE**	Inline XBRL Taxonomy Extension Presentation Linkbase Document.
104	Cover Page Interactive Data File (formatted as Inline XBRL and contained in Exhibit 101).

* Filed herewith.

** Furnished herewith.

SIGNATURES

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 thereunto duly authorized.

Blue Water Vaccines Inc.

Date: November 14, 2022

By: /s/ Joseph Hernandez
Joseph Hernandez
Chairman of the Board and Chief Executive
Officer (principal executive officer)

Date: November 14, 2022

By: /s/ Jon Garfield
Jon Garfield
Chief Financial Officer
(principal financial and accounting officer)

SETTLEMENT AGREEMENT AND RELEASE

This SETTLEMENT AGREEMENT AND RELEASE (“Agreement”) is made and entered into by and between Blue Water Vaccines Inc., a Delaware corporation. (the “Company”) and Boustead Securities, LLC (“Boustead”) on September 28, 2022 (the “Effective Date”). Each of the Company and Boustead is a “Party” under this Agreement, and collectively they constitute the “Parties”. Capitalized terms not otherwise defined herein shall have the meaning set forth in the Underwriting Agreement as defined below.

WHEREAS, the Parties are parties to that certain underwriting agreement, dated as of February 17, 2022, by and between the Company and Boustead (the “Underwriting Agreement”) and that certain engagement letter, dated as of February 7, 2022, by and between the Company and Boustead (the “Engagement Letter” and collectively with the “Underwriting Agreement” called the “Boustead Agreements”);

WHEREAS, Section 4(y) of the Underwriting Agreement and Section 7 of the Engagement Letter entitled Boustead to a right of first refusal to act as the sole underwriter or placement agent for any and all future public and private equity and debt (excluding commercial bank debt) offerings of the Company, or any successor or any Subsidiary of the Company, for a period of twelve (12) months from the date of the Underwriting Agreement. Additionally, Section 4(i) of the Underwriting Agreement restricted the Company, until February 17, 2023, from offering, selling, issuing, agreeing or contracting to sell or issue or grant or modify the terms of any option for the sale of any securities of the Company, subject to certain exceptions;

WHEREAS, the Company subsequently entered into a letter of engagement with H.C. Wainwright & Co., LLC (“HCW”) for certain placement agent services in connection with (i) a private placement transaction (the “First Private Placement”) that was consummated on April 19, 2022; and (ii) a private placement transaction (the “Second Private Placement” and, collectively with the First Private Placement, the “Private Placements”) that was consummated on August 11, 2022, in each case without obtaining Boustead’s consent to such Private Placement and without obtaining a waiver of each of Sections 4(i) and 4(y) of the Underwriting Agreement and Section 7 of the Engagement Letter with respect to such Private Placement and as a result, Boustead alleges that both the First Private Placement and the Second Private Placement constituted a breach of the Company’s obligations under Sections 4(i) and 4(y) of the Underwriting Agreement and Section 7 of the Engagement Letter (the “Dispute”); and

WHEREAS, without admitting any liability as to the foregoing allegations regarding the Dispute, and solely to avoid the cost and uncertainties of litigation over the Dispute, the Parties are entering into this Agreement for the purposes of resolving the Dispute amicably and efficiently.

NOW, THEREFORE, in consideration of the mutual covenants and agreements contained herein, and other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, the Parties agree as follows:

1. Effective Date. This Agreement shall become effective as of the Effective Date, on the condition that the Agreement is executed by both of the Parties, which execution may be in counterparts under Section 20 below.

2. Payments to Be Made and Shares to Be Issued by the Company. In consideration of Boustead entering into this Agreement:

(a) The Company shall pay Boustead \$1,000,000 in immediately available funds via the wiring instructions set forth in Annex A to this Agreement, and such payment shall be made within two business days after full execution of the Agreement by all Parties;

(b) The Company shall issue and deliver to Boustead within five business days after full execution of the Agreement by all Parties, 93,466 shares of restricted Common Stock (the "Restricted Shares") in exchange for the cancellation of that certain Representative Warrant dated February 23, 2022 and termination of all of Company's obligations pursuant thereto. "Common Stock" means the Company shares of common stock, par value \$0.00001 per share.. The Restricted Shares shall be included for registration in the Company's next resale registration statement filed with the SEC ;

(c) The Company shall pay Loeb & Loeb LLP, Boustead's legal counsel ("Loeb"), \$50,000 in immediately available funds via the wiring instructions set forth in Annex B to this Agreement, and such payment shall be made within two business days after full execution of the Agreement by all Parties; Boustead expressly represents that the fees and expenses paid with the foregoing payment were incurred by Boustead in connection with the Dispute and for services rendered to Boustead in connection with a proposed public offering by the Company that was terminated by the Company; and

(d) Time is of the essence with respect to the Company's performance of each of its obligations in Sections 2(a) – (c) above, and the Company's failure to fully satisfy any of those obligations in the time provided in Section 2(a) – (c) for such obligation to be satisfied shall constitute a material breach of this Agreement by the Company.

3. The Company's Representation and Warranty Regarding Other Financing Transactions. The Company represents and warrants to Boustead that, except as set forth in the Company's public filings with the U.S. Securities Exchange Commission ("SEC"), in the period between February 17, 2022 and the Effective Date, the Company has not signed definitive documents with respect to any financing transaction (including but not limited to equity financing, or debt financing transaction), other than the Private Placements.

4. Waiver of Certain Terms of Boustead Agreements. Upon the timely payment by the Company to Boustead and Loeb of the consideration set forth in Section 2(a), 2(b) and 2(c) above, Boustead waives as of the Effective Date the Company's compliance with Sections 4(i) and 4(y) of the Underwriting Agreement and Section 7 of the Engagement Letter with respect to the Company's consummation of the Private Placements and with respect to any and all future private, public equity or debt offerings of the Company. For the avoidance of doubt, upon the Company's compliance with the terms of Section 2(a), 2(b) and 2(c) above, the Parties understand and agree that the Company shall owe no further compensation to Boustead arising from or related to any prior agreement between the Parties, and the Company shall not be subject to any restrictions arising from or related to any prior agreement between the Parties with respect to any future equity, equity-linked, or debt offerings of the Company.

Notwithstanding the foregoing, and except as set forth in this Agreement, the Parties acknowledge and agree that the remaining sections of the Engagement Letter and the Underwriting Agreement, including but not limited to: Section 14 of the Engagement Letter, Section 7 of the Underwriting Agreement, and Section 8 of the Underwriting Agreement, to the extent it pertains to indemnities, shall remain in full force and effect.

5. [Reserved].

6. **Releases of Claims.** Upon timely satisfaction of its obligations pursuant to Sections 2(a), 2(b), and 2(c) of this Agreement, the Company, for itself and its parent companies, subsidiaries, and affiliates and each of its and their past, present, and future officers, directors, members, managers, employees, consultants, attorneys, agents, predecessors, successors, and assigns (collectively the “Company Releasers” and each individually a “Company Releaser”), to the fullest extent permitted by law, hereby irrevocably and unconditionally forever release, waive, and discharge Boustead and its parent companies, subsidiaries, and affiliates and each of its and their past, present, and future officers, directors, members, managers, employees, consultants, attorneys, agents, predecessors, successors, and assigns (collectively the “Boustead Releasees” and each individually a “Boustead Releasee”), from any and all actions, claims, demands, causes of action, and liabilities of any kind whatsoever (upon any legal or equitable theory, whether contractual, common law, statutory, federal, state, local or otherwise), including known or Unknown Claims (as that term is defined in Section 6(d) below), that the Company Releasers, or any of them, has, or hereafter may have, in any jurisdiction or territory, against Boustead Releasees, or any of them, up to and including the Effective Date, for any damage, loss, or injury or for injunctive or other relief, now existing or hereafter arising out of or relating to (i) the Boustead Agreements, and (ii) all other transactions, agreements, contracts, understandings, promises and representations between the Company Releasers and Boustead Releasees, except those provisions that are expressly intended as stated herein to survive.

(b) Upon the timely payment by the Company to Boustead and Loeb of the consideration set forth in Section 2(a), 2(b), and 2(c) above and upon timely satisfaction of its obligations under Section 2 of the Advisory Agreement dated as of September [___], 2022 between the Company and Boustead, Boustead, for itself and its parent companies, subsidiaries, and affiliates and each of its and their past, present, and future officers, directors, members, managers, employees, consultants, attorneys, agents, predecessors, successors, and assigns (collectively the “Boustead Releasers” and each individually a “Boustead Releaser”), to the fullest extent permitted by law, hereby forever release, waive, and discharge the Company and its parent companies, subsidiaries, and affiliates and each of its and their past, present, and future officers, directors, members, managers, employees, consultants, attorneys, agents, predecessors, successors, and assigns (collectively the “Company Releasees” and each individually a “Company Releasee”), from any and all actions, claims, demands, causes of action, and liabilities of any kind whatsoever (upon any legal or equitable theory, whether contractual, common law, statutory, federal, state, local or otherwise), including known or Unknown Claims (as that term is defined in Section 6(d) below), that the Boustead Releasers, or any of them, has, or hereafter may have, in any jurisdiction or territory, against the Company Releasees, or any of them, up to and including the Effective Date, for any damage, loss, or injury or for injunctive or other relief, now existing or hereafter arising out of or relating to (i) the Boustead Agreements, and (ii) all other transactions, agreements, contracts, understandings, promises and representations between Boustead Releasers and the Company Releasees, except those provisions that are expressly intended as stated herein to survive. For purposes of clarity, none of the Boustead Releasers is releasing, waiving, or discharging pursuant to this Section 6(b) any claims, demands, causes of action, or liabilities of any kind what so ever against any of the Company Releasees arising under (1) Section 14 of the Engagement Letter, (2) Section 7 of the Underwriting Agreement, (3) Section 8 of the Underwriting Agreement, to the extent it pertains to indemnities or (4) the Advisory Agreement.

(c) [Reserved]

(d) “Unknown Claims” means any and all claims and causes of action for any damage, loss, or injury or for injunctive or other relief arising out of or relating to the Boustead Agreements that a Party does not know, does not suspect, or does not have reason to know or to suspect exist in its favor at any time on or before the Effective Date, including any such claim or cause of action for new or additional damages or injuries that, if known, might have affected the decision to enter into this Agreement.

(e) Claims Arising Out of Breach of this Agreement. For avoidance of doubt, nothing contained herein shall release or discharge any claim that either Party may have arising out of a breach of the other Party’s obligations under this Agreement.

7. Representations and Warranties. Each Party hereby represents and warrants to the other Party that: (i) the Party has the right and authority to grant the releases and confer the rights contemplated by this Agreement; (ii) the person signing this Agreement is duly authorized to enter into this Agreement on the Party’s behalf; and (iii) the Party is not relying on any representation, by or on behalf of any other Party, not expressly set forth in this Agreement and that no such representation has been made to it by or on behalf of any other Party.

8. Confidentiality. Each of the Parties acknowledges and agrees that, except for the fact that the Boustead Agreements have been terminated subject to the provisions in this Agreement, the terms and conditions of this Agreement, the discussions that led up to this Agreement, and the amount and form of consideration provided for in this Agreement (together, the “Confidential Information”) are confidential and sensitive information, and each Party represents and agrees that it will not disclose any Confidential Information except as necessary to its respective parent companies, corporate affiliates, officers, directors, employees, attorneys, auditors, or as otherwise required by law, subpoena, regulator request, or other legal process. Notwithstanding anything in this Agreement to the contrary, if any Party is required by a court or regulatory authority in connection with a legal or administrative proceeding to disclose this Agreement, any term hereof, or any Confidential Information, such Party shall, to the extent legally permitted, provide the other Party with prompt notice of such requirement (within no more than five (5) business days if reasonably possible) so that the other Party may seek, at its sole expense, a protective order or other appropriate remedy. If such protection or other remedy is not obtained or as otherwise required by law, the Party may make such disclosure that it is required to disclose. Notwithstanding the above, the Company shall be permitted to disclose in its filings with the SEC that the Parties have entered into this Agreement as well as the material terms hereof.

9. No Admission. The Parties have entered into this Agreement solely for the purpose of avoiding the burdens and expense of litigation over the Dispute. The making of this Agreement is not intended, and shall not be construed, as any acknowledgment or admission of the existence or non-existence of any fact, or that any Party had or did not have any valid claim arising under any federal, state, or local law (statutory or decisional), ordinance, or regulation, or has committed or not committed any other actionable wrong against any other Party.

10. Entire Agreement and Amendments. This Agreement constitutes the full and entire understanding and agreement between the Parties with regard to the subject matter of this Agreement and supersedes and terminates any and all prior oral or written agreements, understandings, representations and warranties, and courses of conduct and dealing among the Parties with regard to the subject matter of this Agreement, other than as set forth in this Agreement. Any termination, amendment, modification or change of this Agreement may be made only by a writing signed by the Parties.

11. Non-Disparagement. Each Party agrees that its shall make no statements, remarks or comments, orally or in writing, publicly or privately, to any third party that would constitute actionable defamation with regard to (a) the other Party, (b) the other Party's products, services, or business, or (c) the other Party's current or former management, officers, directors, shareholders, members, employees, agents, or attorneys, provided, however, that neither Party shall be restricted from providing information about any of the entities or things described in (a), (b), or (c), as required by a court or governmental agency or by applicable law. The Parties agree that this Section 11 is a material term of this Agreement.

12. Governing Law; Submission to Jurisdiction; Venue. This Agreement shall be governed by and construed *exclusively* in accordance with the laws of the State of New York, without regard to any conflicts of law provisions which would require the application of the law of any jurisdiction other than the State of New York. Each of the Parties hereby consents to the exclusive personal jurisdiction and venue of the state and federal courts of competent subject-matter jurisdiction sitting in New York County, New York for any disputes arising from, or relating to, this Agreement.

13. Notice. Except as otherwise specified herein, any notices pertaining to the Agreement shall be in writing and shall be deemed to have been duly given when delivered in person, by FedEx or similar receipted delivery, by email, or by fax to the following representatives:

If to the Company:

Blue Water Vaccines Inc.
201 E. Fifth Street, Suite 1900
Cincinnati, Ohio 45202 Attn: Joseph Hernandez, CEO
Email: hernandez_joe@yahoo.com

with a copy (which shall not constitute notice) to:
Ellenoff Grossman & Schole LLP
1345 Avenue of the Americas, 11th Floor
New York, New York 10105
Attention: Barry I. Grossman, Esq.
Fax: 212-370-7889]

If to Boustead:

Boustead Securities, LLC
6 Venture, Suite 395
Irvine, CA 92618 Attn: Keith Moore
Email: keith@boustead1828.com

with a copy (which shall not constitute notice) to:

Loeb & Loeb LLP
345 Park Avenue
New York, New York 10154
Attention: Mitchell Nussbaum, Esq.
Fax: 212-407-4990

14. Binding Effect. This Agreement is binding upon, and shall inure to the benefit of, the Parties and their respective heirs, successors and assigns.

15. No Assignment. No Party may assign any rights or obligations hereunder, except with the express written consent of the other Parties hereto, and any attempted assignment or transfer without such consent shall be null and void.

16. No Credit for Drafting. The Parties agree that the drafting of this Agreement was the result of negotiations between the Parties and none of the Parties will be deemed the drafter of any portion of this Agreement for purposes of its construction and interpretation. Each Party acknowledges and represents that it has reviewed this Agreement with that Party's respective counsel and that each Party understands the terms of this Agreement.

17. No Waiver. No waiver by any Party of any provision or condition of this Agreement at any time shall be deemed a waiver of such provision or condition at any prior or subsequent time or of any other provision or condition at the same or any prior or subsequent time.

18. Expenses. Except as provided in Section 2(c) of this Agreement, each Party shall pay all of its own expenses (including, without limitation, attorneys' fees, expenses and costs) incurred by it in connection with this Agreement and the negotiations that led to it.

19. Severability. If any provision of this Agreement is held to be illegal, void or unenforceable, such provision shall be of no force and effect. The illegality or unenforceability of such provision shall have no effect upon, and shall not impair the enforceability of, any other provision of this Agreement, provided, however, that if:

(a) Section 6(a) is held to be illegal, invalid, or unenforceable, in whole or in part, then the Company, for itself and the other Company Releasors, agrees to promptly execute a legal, valid, and enforceable release and waiver of claims, on its own behalf and behalf of the other Company Releasors, in favor of the Boustead Releasees corresponding to the scope of the release and waiver of claims provided in Section 6(a), and, in the event that such a legal, valid, and enforceable release and waiver of claims cannot be obtained, then the Company and the other Company Releasors shall be deemed to have assigned, transferred, and conveyed the claims described in Section 6(a) to Boustead; or,

(b) Section 6(b) is held to be illegal, invalid, or unenforceable, in whole or in part, then Boustead, for itself and the other Boustead Releasers, agrees to promptly execute a legal, valid, and enforceable release and waiver of claims, on its own behalf and behalf of the other Boustead Releasers, in favor of the Company Releasees corresponding to the scope of the release and waiver of claims provided in Section 6(b), and, in the event that such a legal, valid, and enforceable release and waiver of claims cannot be obtained, then Boustead and the other Boustead Releasers shall be deemed to have assigned, transferred, and conveyed the claims described in Section 6(b) to the Company.

20. Counterparts. This Agreement may be executed in two or more identical counterparts, each of which shall be an original, but all of which together shall constitute one instrument. It is further agreed by the Parties that facsimile and electronic signatures will be deemed as originals.

21. Obligations. Notwithstanding anything herein to the contrary, the Parties hereby agree that no provision of this Agreement shall require any Party to do any act that violates any law, regulation, or rule of professional responsibility.

22. Headings. All headings used herein are solely for convenience and shall not be used to interpret the Agreement.

23. Legal Counsel Opinions. For any of the shares of Common Stock that Boustead or its designee is entitled to receive under this Agreement including but not limited to the shares of Common Stock described in Section 2 of this Agreement (collectively the "Boustead Securities"), and upon the request of Boustead, which it may make from time to time, the Company shall be responsible (at its cost) for promptly supplying to the Company's transfer agent and Boustead a customary legal opinion letter of its counsel (the "Legal Counsel Opinion") to the effect that the resale of the Boustead Securities by Boustead, its designee or their respective affiliates, successors and assigns is exempt from the registration requirements of the Securities Act of 1933, as amended (the "Securities Act"), pursuant to Rule 144 (provided the requirements of Rule 144 are satisfied and provided the Boustead Securities are not then registered under the Securities Act for resale pursuant to an effective registration statement). Alternatively, at Boustead's option, Boustead may (at Boustead's cost) secure another legal counsel to issue the Legal Counsel Opinion, and the Company will promptly instruct its transfer agent (or the transfer agent of its acquiror as the case may be) to accept such opinion. The Company shall not impede the removal by its stock transfer agent of the restricted legend from any common stock certificate upon receipt by the transfer agent of a Rule 144 Opinion Letter. **THE COMPANY HEREBY AGREES THAT, FOR A PERIOD OF THREE (3) YEARS FOLLOWING THE DATE OF THIS AGREEMENT, IT WILL NOT TAKE THE POSITION THAT IT IS A "SHELL COMPANY" UNLESS, ON ADVICE OF ITS COUNSEL, IT IS REQUIRED TO TAKE SUCH POSITION AS A MATTER OF APPLICABLE LAW.**

24. Further Assurances. The Parties agree to take all actions and to make, deliver, and/or sign any other documents and instruments that are reasonably necessary to carry out the terms, provisions, purpose, and intent of this Agreement.

25. Costs of Enforcement. In the event of any litigation or proceeding arising as a result of the breach of this Agreement or the failure to perform hereunder, the Party prevailing in such litigation or proceeding shall be entitled to collection costs, court costs, reasonable attorneys' fees, and all other expenses of bringing or defending such litigation or proceeding, from the Party not prevailing.

[Signature Page Follows]

IN WITNESS WHEREOF, the Parties hereto have caused this Agreement to be signed by their duly authorized representatives as of the date indicated below:

BLUE WATER VACCINES, INC.

By: /s/ Joseph Hernandez
Name: Joseph Hernandez
Title: CEO

Date signed: October 9, 2022

Authorized to enter into this Agreement on behalf of Blue Water Vaccines Inc.

BOUSTEAD SECURITIES, LLC

By: /s/ Keith Moore
Name: Keith Moore
Title: CEO

Date signed: September 28, 2022

Authorized to enter into this Agreement on behalf of Boustead Securities, LLC

**CERTIFICATION OF THE
PRINCIPAL EXECUTIVE OFFICER
PURSUANT TO
RULE 13a-14(a) AND RULE 15d-14(a)
UNDER THE
SECURITIES EXCHANGE ACT OF 1934,
AS ADOPTED PURSUANT TO
SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002**

I, Joseph Hernandez, hereby certify that:

1. I have reviewed this Quarterly Report on Form 10-Q for the quarter ended September 30, 2022 of Blue Water Vaccines Inc.
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) for the registrant and have:
 - a. Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
 - b. (Paragraph omitted pursuant to SEC Release Nos. 33-8238/34-47986 and 33-8392/34-49313);
 - c. Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
 - d. Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors:
 - a. All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
 - b. Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: November 14, 2022

/s/ Joseph Hernandez

Joseph Hernandez
Chief Executive Officer

**CERTIFICATION OF THE
PRINCIPAL FINANCIAL OFFICER
PURSUANT TO
RULE 13a-14(a) AND RULE 15d-14(a)
UNDER THE
SECURITIES EXCHANGE ACT OF 1934,
AS ADOPTED PURSUANT TO
SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002**

I, Jon Garfield, hereby certify that:

1. I have reviewed this Quarterly Report on Form 10-Q for the quarter ended September 30, 2022 of Blue Water Vaccines Inc.
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) for the registrant and have:
 - a. Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
 - b. (Paragraph omitted pursuant to SEC Release Nos. 33-8238/34-47986 and 33-8392/34-49313);
 - c. Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
 - d. Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors:
 - a. All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
 - b. Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: November 14, 2022

/s/ Jon Garfield

Jon Garfield
Chief Financial Officer

CERTIFICATION
Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002
(18 U.S.C. 1350)

Pursuant to Section 906 of the Sarbanes-Oxley Act of (18 U.S.C. 1350), the undersigned officer of Blue Water Vaccines Inc., a Delaware corporation (the "Company"), does hereby certify, to the best of such officer's knowledge and belief, that:

- (1) The Quarterly Report on Form 10-Q for the period ended September 30, 2022 (the "Form 10-Q") of the Company fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended; and
- (2) The information contained in the Form 10-Q fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: November 14, 2022

/s/ Joseph Hernandez
Joseph Hernandez,
Chief Executive Officer

CERTIFICATION
Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002
(18 U.S.C. 1350)

Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002 (18 U.S.C. 1350), the undersigned officer of Blue Water Vaccines Inc., a Delaware corporation (the "Company"), does hereby certify, to the best of such officer's knowledge and belief, that:

- (1) The Quarterly Report on Form 10-Q for the period ended September 30, 2022 (the "Form 10-Q") of the Company fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended; and
- (2) The information contained in the Form 10-Q fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: November 14, 2022

/s/ Jon Garfield

Jon Garfield,
Chief Financial Officer