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 March 31, 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	**81-2262816**
(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification No.)
201 E. Fifth Street, Suite 1900 Cincinnati, OH	**45202**
(Address of principal executive offices)	(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 ☐ Accelerated filer ☐ Non-accelerated filer ☒ Smaller reporting company ☒
Emerging growth company ☒

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

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 May 12, 2022, the registrant had 11,638,993 shares of common stock, $0.00001 par value per share, outstanding.

TABLE OF CONTENTS

		Page
	Cautionary Note Regarding Forward-Looking Statements	ii
PART I.	FINANCIAL INFORMATION	1
Item 1.	Condensed Financial Statements (unaudited).	1
	Condensed Balance Sheets	1
	Condensed Statements of Operations	2
	Condensed Statements of Stockholders' Equity	3
	Condensed Statements of Cash Flows	4
Item 2.	Management's Discussion and Analysis of Financial Condition and Results of Operations.	21
Item 3.	Quantitative and Qualitative Disclosures About Market Risk.	33
Item 4.	Controls and Procedures.	33
PART II.	OTHER INFORMATION	35
Item 1.	Legal Proceedings.	35
Item 1A.	Risk Factors.	35
Item 2.	Unregistered Sales of Equity Securities and Use of Proceeds.	35
Item 3.	Defaults Upon Senior Securities.	35
Item 4.	Mine Safety Disclosures.	35
Item 5.	Other Information.	35
Item 6.	Exhibits.	36
	Signatures	37

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

	March 31, 2022	December 31, 2021
ASSETS	**(Unaudited)**	
Current assets		
Cash	$ 18,609,249	$ 1,928,474
Prepaid expenses	90,005	234,551
Deferred offering costs	238,804	757,646
Receivable from related parties	164,515	152,524
Total current assets	19,102,573	3,073,195
Prepaid expenses, long-term	129,454	—
Property and equipment, net	15,399	11,502
Deposit	87,638	—
Total assets	**$ 19,335,064**	**$ 3,084,697**
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities		
Accounts payable	$ 907,538	$ 582,605
Accrued expenses	1,893,438	1,055,515
Total current liabilities	2,800,976	1,638,120
Commitments and Contingencies (see Note 7)		
Stockholders' equity		
Preferred stock, $0.00001 par value, 10,000,000 shares authorized at March 31, 2022 and December 31, 2021		
Series Seed: 0 and 1,150,000 shares designated at March 31, 2022 and December 31, 2021, respectively; 0 and 1,146,138 shares issued and outstanding at March 31, 2022 and December 31, 2021, respectively; $0 and $15.4 million aggregate liquidation preference at March 31, 2022 and December 31, 2021, respectively	—	11
Common stock, $0.00001 par value, 250,000,000 shares authorized at March 31, 2022 and December 31, 2021; 11,048,587 and 3,200,000 shares outstanding at March 31, 2022 and December 31, 2021, respectively	110	32
Additional paid-in-capital	24,561,309	7,403,204
Accumulated deficit	(8,027,331)	(5,956,670)
Total stockholders' equity	16,534,088	1,446,577
Total liabilities and stockholders' equity	**$ 19,335,064**	**$ 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 March 31, 2022	Three Months Ended March 31, 2021
Operating costs and expenses		
General and administrative	$ 1,615,569	$ 237,544
Research and development	455,092	88,237
Total operating expenses	2,070,661	325,781
Loss from operations	(2,070,661)	(325,781)
Net loss	**$ (2,070,661)**	**$ (325,781)**
Cumulative preferred stock dividends	96,359	137,687
Net loss applicable to common stockholders	(2,167,020)	(463,468)
Net loss per share attributable to common stockholders, basic and diluted	$ (0.34)	$ (0.14)
Weighted average number of common shares outstanding, basic and diluted	6,339,435	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	Accumulated	Total Stockholders'
	Shares	Amount	Shares	Amount	Capital	Deficit	Equity
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**

	Preferred Stock		Common Stock		Additional Paid-in	Accumulated	Total Stockholders'
	Shares	Amount	Shares	Amount	Capital	Deficit	Equity
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**

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

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

	Three Months Ended March 31, 2022	Three Months Ended March 31, 2021
Cash flows from operating activities		
Net loss	$ (2,070,661)	$ (325,781)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation expense	1,300	1,232
Stock-based compensation	19,332	41,721
Changes in assets and liabilities:		
Prepaid expenses	144,546	(57,309)
Receivable from related parties	(11,991)	(5,056)
Prepaid expenses, long-term	(129,454)	46,233
Deposit	(87,638)	—
Accrued expenses	896,659	—
Accounts payable	351,816	42,412
Net cash used in operating activities	(886,091)	(256,548)
Cash flows from investing activities		
Purchase of property and equipment	(5,197)	—
Net cash used in investing activities	(5,197)	—
Cash flows from financing activities		
Payment of deferred offering costs	(5,000)	—
Proceeds from issuance of common stock in initial public offering, net of underwriting discount	18,400,000	—
Payments of initial public offering costs	(822,937)	—
Net cash provided by financing activities	17,572,063	—
Net increase (decrease) in cash	16,680,775	(256,548)
Cash, beginning of period	1,928,474	4,308,821
Cash, end of period	$ 18,609,249	$ 4,052,273
Noncash investing and financing activities:		
Deferred offering costs included in accounts payable and accrued expenses	$ 233,804	$ —
Conversion of convertible preferred stock to common stock upon initial public offering	$ 45	$ —
Initial public offering costs included in accounts payable	$ 104,035	$ —

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 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.

The Company has incurred substantial operating losses since inception and expects to continue to incur significant operating losses for the foreseeable future. As of March 31, 2022, the Company had cash of approximately $18.6 million, working capital of approximately $16.3 million and an accumulated deficit of approximately $8.0 million.

On April 19, 2022, the Company completed a private placement in which it received approximately $7.0 million in net proceeds, after deducting placement agent fees and other initial offering expenses, see Note 11. The Company believes the existing cash at March 31, 2022, together with the net proceeds received upon the close of the private placement, 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 months ended March 31, 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.

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, 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 March 31, 2022, and the condensed statements of operations, the condensed statements of changes in stockholders' equity, and the condensed statements of cash flows for the three months ended March 31, 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 March 31, 2022 and its results of operations and cash flows for the three months ended March 31, 2022 and 2021. The financial data and the other financial information disclosed in the notes to these condensed financial statements related to the three-month periods are also unaudited. Operating results for the three months ended March 31, 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 March 31, 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.

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

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;
- 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 parties, accounts payable and accrued liabilities are carried at cost, which management believes approximates fair value due to the short-term nature of these instruments. None of the Company's non-financial assets or liabilities are recorded at fair value on a non-recurring basis.

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 March 31, 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.

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.

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, and with historical share price information sufficient to meet the expected term of the stock-based awards.

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 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;

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 March 31, 2022, all of the Company's outstanding warrants are equity-classified warrants.

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. 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.

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

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 March 31,	
	2022	**2021**
Options to purchase shares of common stock	780,640	780,640
Series Seed Preferred Stock	—	4,584,552
Warrants to purchase shares of common stock	111,111	—
Total	**891,751**	**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 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

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

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.

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.

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 March 31, 2022 and December 31, 2021:

	As of March 31, 2022	As of December 31, 2021
Prepaid research and development	$ 69,205	$ 203,910
Prepaid insurance	—	4,842
Prepaid other	20,800	25,799
Total	**$ 90,005**	**$ 234,551**

Note 4 — Balance Sheet Details (cont.)

Accrued Expenses

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

	As of March 31, 2022	As of December 31, 2021
Accrued license fees	$ 227,500	$ 225,000
Accrued research and development	564,634	300,182
Accrued deferred offering costs	187,500	246,236
Accrued compensation	680,537	234,265
Accrued insurance expense	118,988	—
Accrued board of directors' compensation	33,750	—
Accrued other	80,529	49,832
Total	**$ 1,893,438**	**$ 1,055,515**

Note 5 — Significant Agreements

Oxford University Innovation Limited

In December 2018, the Company entered into an option agreement 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 months ended March 31, 2022. Either party may terminate the OUI Agreement for an uncured material breach. The Company may terminate the OUI Agreement for any reason at any time upon six months' written notice expiring after 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 months ended March 31, 2022 and 2021, the Company did not incur any licensing fee payments for intellectual property licenses. See Note 7.

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, milestones payments and licensing fees were amended. See Note 11 for more information on this amendment.

For the three months ended March 31, 2022, the Company recognized approximately $3,000 for intellectual property licenses, which is recorded as research and development expenses. For the three months ended March 31, 2021, the Company did not incur any licensing fee payments for intellectual property licenses. 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 reimburse CHMC for its costs, including reasonable attorneys' fees.

Note 5 — Significant Agreements (cont.)

For the three months ended March 31, 2022 and 2021, the Company did not incur any licensing fee payments for intellectual property licenses. 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 March 31, 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. During the three months ended March 31, 2022, the Company incurred related research and development expenses of approximately $217,000, and had approximately $332,000 recorded as related accrued expenses at March 31, 2022. See Note 4. There were no such expenses incurred during the three months ended March 31, 2021. On April 20, 2022, the Company entered into an amendment to the Ology MSA, whereby the Company's obligations increased by $0.3 million, specifically related to regulatory support on the project. See Note 11.

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 March 31, 2022 and December 31, 2021, there were 11,048,587 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. The warrants are exercisable, at the option of the holder, at a per share exercise price equal to $10.35 and are 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.

The Company evaluated the terms of the warrants issued at 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. As of March 31, 2022, the outstanding warrants are exercisable into 111,111 shares of common stock whose fair value was $56.50 per share, based on the closing trading price on that day.

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 March 31, 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 October 7, 2021, 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

Note 6 — Stockholders' Equity (cont.)

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.

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 months ended March 31, 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. As of March 31, 2022, there were no share-based awards granted under the 2022 Plan.

Note 7 — Commitments and Contingencies

Office lease

The Company leased office space for approximately $5,500 a month from a related party. The Company paid a $15,000 rental deposit and rent expense for the three months ended March 31, 2022 and 2021 was approximately $0 and $20,000, respectively. The Company terminated the related party lease in May 2021 and entered into a new lease with an unrelated party in April 2021. The Company is not a party to a lease with a term in excess of 12 months and has a month-to-month lease as of March 31, 2022.

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 March 31, 2022, the Company is not a party to any material legal proceedings and is not aware of any pending or threatened claims. See Note 11.

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

Note 7 — Commitments and Contingencies (cont.)

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 March 31, 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 March 31, 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 March 31, 2022 and December 31, 2021.

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. Specifically, the Company is obligated to make 4% 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 required to pay 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 million; specifically, upon the achievement of specified development milestones of approximately $0.2 million, regulatory milestones of approximately $0.3 million, and commercial milestones of approximately $0.5 million. 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. See Note 11 for more information on this amendment. As of March 31, 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 March 31, 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. Pursuant to this research agreement, 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. During the three months ended March 31, 2022, the Company incurred related research and development expenses of approximately $8,000, and had approximately $15,000 recorded as related accrued expenses at March 31, 2022. There were no such expenses incurred during the three months ended March 31, 2021.

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

Note 7 — Commitments and Contingencies (cont.)

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 March 31, 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 March 31, 2022.

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. During the three months ended March 31, 2022, the Company incurred related research and development expenses of approximately $217,000, and had approximately $332,000 recorded as related accrued expenses at March 31, 2022. See Note 4. There were no such expenses incurred during the three months ended March 31, 2021. This project is currently expected to be performed through the fourth quarter of 2023. On April 20, 2022, the Company entered into an amendment to the Ology MSA, whereby the Company's obligations increased by $0.3 million, specifically related to regulatory support on the project. See Note 11.

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 during the three months ended March 31, 2022, and is included in accounts payable in the accompanying condensed balance sheet at March 31, 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.

Note 8 — Related Party Transactions

The Company originally engaged the Chief Executive Officer, 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 calls for the Company to pay for consulting services performed on a monthly basis. During the three months ended March 31, 2022 and 2021, the Company incurred approximately $63,000 and $105,000 in fees under the consulting agreement, respectively, which are recognized in general and administrative expenses in the accompanying statements of operations. Upon the close of the Company's IPO, the consulting agreement was terminated and the CEO's employment agreement became effective.

Note 8 — Related Party Transactions (cont.)

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 parties balance.

As of March 31, 2022 and December 31, 2021, the Company has a receivable from related parties of approximately $165,000 and $153,000, respectively. The balance consists primarily of consulting fee prepayments to the Company's CEO, in the amount of $140,000 as of March 31, 2022 and December 31, 2021. 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 March 31, 2022 consists of approximately $18,000 and $7,000 of miscellaneous payments made by the Company on the behalf of the CEO and Chief Business Officer, respectively. The balance due from the Chief Business Officer was repaid to the Company in April 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 directors 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 months ended March 31, 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 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 months ended March 31, 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. Enrollment in the 401(k) Plan will become available during the second quarter of 2022. No expenses were incurred related to the 401(k) Plan during the three months ended March 31, 2022.

Note 11 — Subsequent Events

On April 19, 2022, the Company consummated the closing of a private placement (the "Private Placement"), pursuant to the terms and conditions of a securities purchase agreement, dated as of April 13, 2022. At the closing of the Private Placement, the Company issued 590,406 shares of common stock (the "Shares"), pre-funded warrants (the "Pre-Funded Warrants") to purchase an aggregate of 590,406 shares of common stock and preferred investment options (the "Preferred Investment Options") to purchase up to an aggregate of 1,180,812 shares of common stock. The purchase price of each Share 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 proceeds to the Company from the Private Placement were approximately $7.0 million, after deducting placement agent fees and other initial offering expenses. H.C. Wainwright & Co., LLC ("Wainwright") acted as the exclusive placement agent for the Private Placement. The Pre-Funded Warrants have an exercise price of $0.001 per share, are exercisable on or after April 19, 2022, and are exercisable until the Pre-Funded Warrants are exercised in full. The Preferred Investment Options are exercisable at any time on or after April 19, 2022 at an exercise price of $6.65 per share, subject to certain adjustments as defined in the agreement. 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 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 "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. Further, upon any exercise for cash of any Preferred Investment Options, the Company agreed to issue to Wainwright warrants to purchase the number of Shares equal to 6.0% of the aggregate number of Shares underlying the Preferred Investment Options that have been exercised, also with an exercise price of $8.46875.

In connection with the Private Placement, the Company entered into a Registration Rights Agreement with the purchasers, dated as of April 13, 2022 (the "Registration Rights Agreement"). The 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 Registration Rights Agreement) with the Securities and Exchange Commission (the "SEC") no later than the 20th calendar day following the date of the 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.

Upon the occurrence of any Event (as defined in the 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, 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 Private Placement.

On April 15, 2022, the Company received a demand letter (the "Demand Letter") from Boustead. The Demand Letter alleges 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 alleges that, by engaging Wainwright as placement agent in the Private Placement, the Company breached the right of first refusal to act as placement agent granted to Boustead under the Underwriting Agreement and, as a result of selling securities in the Private Placement, breached the 12-month lock-up obligation following the consummation of the initial public offering under the Underwriting Agreement. The Demand Letter requested that the Company rescind the Private Placement. The Company has not responded to the Demand Letter and no legal action has been brought by Boustead to date. There can be no assurance as to whether any litigation will be commenced against the Company with respect to the demand letter or that, if any such litigation is commenced, the Company will not incur material losses due to damages, penalties, costs and/or expenses as a result of such litigation or that any such losses will not have a material impact on the Company's financial condition or results of operations.

On April 20, 2022, the Company and Ology entered into a first amendment to the second Project Addendum (the "Ology Amendment"), see Notes 5 and 7. 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 May 4, 2022, the Company's compensation committee approved stock option grants under the Company's 2022 Equity Incentive Plan to the Company's executive officers, board members, employees and certain consultants. The stock options granted 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.

On May 11, 2022, the Company and St. Jude entered into a first amendment to the St. Jude Agreement (the "St. Jude Amendment"), see Notes 5 and 7. 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.

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 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 a private placement. 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 March 31, 2022, the Company had working capital of approximately $16.4 million and an accumulated deficit of approximately $7.9 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 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 a first 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.

For additional details regarding our relationship with Ology, see Notes 5, 7 and 11 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:

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.

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:

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, 7 and 11 to our financial statements included elsewhere in this Report. The St. Jude license includes:

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.

COVID-19 Impacts

We are continuing to closely monitor the impact of the global COVID-19 pandemic on our business and are taking proactive efforts designed to protect the health and safety of our employees and to maintain business continuity. We believe that the measures we are implementing are appropriate, and we will continue to monitor and seek to comply with guidance from governmental authorities and adjust our activities as appropriate. Based on guidance issued by federal, state and local authorities, we transitioned to a remote work model for a vast majority of our employees in March 2020. The COVID-19 pandemic has resulted in an impact to our development timelines, as the pandemic continues, we could continue to see an impact on our ability to advance our programs, obtain supplies from our contract manufacturer or interact with regulators, ethics committees or other important agencies due to limitations in regulatory authority, employee resources or otherwise. In any event, if the COVID-19 pandemic continues and persists for an extended period of time, we could experience significant disruptions to our development timelines, which would adversely affect our business, financial condition, results of operations and growth prospects.

In addition, while the potential economic impact brought by, and the duration of, the COVID-19 pandemic may be difficult to assess or predict, the pandemic could result in significant and prolonged disruption of global financial markets, reducing our ability to access capital, which could in the future negatively affect our liquidity. In addition, a recession or market correction resulting from the spread of COVID-19 could materially affect our business and the potential value of our common stock.

The extent of the impact of the COVID-19 pandemic on our development and regulatory efforts, our ability to raise sufficient additional capital on acceptable terms, if at all, and the future value of and market for our common stock will depend on future developments that are highly uncertain and cannot be predicted with confidence at this time, such as the ultimate duration of the pandemic, travel restrictions, quarantines, social distancing and business closure requirements in the U.S. and in other countries, and the effectiveness of actions taken globally to contain and treat COVID-19. For additional information about risks and uncertainties related to the COVID-19 pandemic that may impact our business, financial condition and results of operations, see the section titled “Risk Factors.”

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 increase 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 March 31, 2022 and 2021

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

	Three Months Ended March 31, 2022	Three Months Ended March 31, 2021	$ Change	% Change
Operating costs and expenses				
General and administrative	$ 1,615,569	$ 237,544	1,378,025	580.1%
Research and development	455,092	88,237	366,855	415.8%
Total operating expenses	2,070,661	325,781	1,744,880	535.6%
Loss from operations	(2,070,661)	(325,781)	(1,744,880)	535.6%
Net loss	$ (2,070,661)	$ (325,781)	(1,744,880)	535.6%

General and Administrative Expenses

For the three months ended March 31, 2022, general and administrative expenses increased by $1.4 million compared to the same period in 2021. The increase was mainly due to an increase in employee and director compensation, including annual bonus compensation, of approximately $0.5 million, an increase in audit, accounting, and legal services of $0.3 million, and increases in other business activities related to now being a public company of $0.2 million. In addition, during the three months ended March 31, 2022, the Company incurred $0.3 million for a non-recurring termination penalty to the Company's former underwriter, to early terminate the agreement with that underwriter.

Research and Development Expenses

For the three months ended March 31, 2022, research and development expenses increased by approximately $0.4 million compared to the same period in 2021. The increase was primarily attributable to an increase in preclinical development activities of approximately $0.3 million mainly related to BWV-201, and an increase in research and development personnel costs of approximately $0.1 million.

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 $2.1 million for the three months ended March 31, 2022. As of March 31, 2022, we had an accumulated deficit of $8.0 million. We also generated negative operating cash flows of $0.9 million for the three months ended March 31, 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 a private placement in which we received approximately $7.0 million in net proceeds, after deducting placement agent fees and other initial offering expenses. The Company believes the existing cash at March 31, 2022, together with the net proceeds received upon the close of the private placement, 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 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 March 31, 2022, together with the net proceeds received from the private placement, 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:

	Three Months Ended March 31, 2022	Three Months Ended March 31, 2021
Net cash used in operating activities	(886,091)	(256,548)
Net cash used in investing activities	(5,197)	—
Net cash provided by financing activities	17,572,063	—
Net increase (decrease) in cash	16,680,775	(256,548)

Cash Flows from Operating Activities

Net cash used in operating activities for the three months ended March 31, 2022 was $0.9 million, which primarily resulted from a net loss of $2.1 million, and was partially offset by a net change in our operating assets and liabilities of $1.2 million.

Net cash used in operating activities for the three months ended March 31, 2021 was $0.3 million, which primarily resulted from a net loss of $0.3 million.

Cash Flows from Investing Activities

Net cash used in investing activities for the three months ended March 31, 2022 was $5,000, which resulted from purchases of property and equipment. There were no such purchases, or other investing activities during the three months ended March 31, 2021.

Cash Flows from Financing Activities

Net cash provided by financing activities for the three months ended March 31, 2022 was $17.6 million, and resulted primarily from the close of our IPO. No financing activities took place during the three months ended March 31, 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, 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.

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, and with historical share price information sufficient to meet the expected term of the stock-based awards.

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 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

Stock Options

On May 4, 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, board members, employees and certain consultants.

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.

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 March 31, 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 March 31, 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. Further, we have designed an approval policy and certain controls surrounding the identification, approval and reporting of related party transactions, that we expect to implement during 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 March 31, 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 May 3, 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.

Item 3. Default Upon Senior Securities

None.

Item 4. Mine Safety Disclosures

Not applicable.

Item 5. Other Information

None.

Item 6. Exhibits, Financial Statement Schedules.

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

EXHIBIT INDEX

Exhibit Number	Description of Document
10.1	Amendment No. 1 to Project Addendum 2 to Master Services Agreement, dated as of April 20, 2022, by and between the Registrant and Ology Bioservices, Inc.
10.2	Amendment #1 to Exclusive License Agreement, dated as of May 11, 2022, by and between the Registrant and St. Jude Children's Research Hospital, Inc.
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).

* 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: May 13, 2022

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

Date: May 13, 2022

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

Exhibit 10.1

AMENDMENT 1 TO PROJECT ADDENDUM 2 TO MASTER SERVICES AGREEMENT

This Amendment 1 (the "Amendment") is effectively dated as of January 11, 2022 (the "Effective Date") by and between Blue Water Vaccines, Inc., a Delaware corporation having a principal place of business at 15 East Putnam Avenue, Suite 363, Greenwich, CT 06830 ("Blue Water" or "Client"), and Ology Bioservices, Inc., a Delaware corporation having a principal place of business at 13200 NW Nano Court, Alachua, Florida 32615 ("Ology Bio"). Blue Water and Ology Bio are sometimes referred to herein individually as a "Party" and collectively as the "Parties."

WHEREAS, Blue Water and Ology Bio entered into a Master Services Agreement effectively dated as of July 19, 2019 (the "MSA") whereby Ology Bio agreed to provide, from time to time, services and deliverables associated therewith to Client pursuant to the terms and conditions set forth in the MSA and any Project Addendum;

WHEREAS, Blue Water and Ology Bio entered into Project Addendum II dated May 21, 2021 ("PA II"); and WHEREAS, the Parties desire to amend PA II in the manner described herein.

NOW, THEREFORE, in consideration of the foregoing and the mutual promises, covenants and agreements set forth below, and for other good and valuable consideration, the receipt and sufficiency of which the parties hereby acknowledge, the Parties agree as follows:

Amendment

The Parties agree to Amend PA II by adding Task 9, as set forth below, to provide additional regulatory support to Blue Water .

Task 9: Regulatory Support

Ology Bio Regulatory will provide CMC support to Client, including preparing all CMC documents for submission in a regulatory application to the US FDA (i.e., Module 2 and Module 3 Quality Information). The CMC information will be prepared for Client according to FDA and ICH guidance using templates that provide consistent granularity for products in clinical development. Regulatory will provide CMC sections in CTD format in Microsoft Word documents along with a letter of authorization (cross reference) to the ADM Alachua Florida Type 5 Site Master File to support the facility section (3.2.A). CMC writing to support pre-submission briefing packages is included. The CMC information will support a Master File or IND submission as desired by Client. If the application is for non-US dossiers, a facility section will be provided in the CMC to support regulatory filings.

Ology Bio Tier 2 Support shall include:

- Review of key CMC documents to determine if supportive of product intended use, including specifications/batch analysis, DS and DP release and stability protocols/reports. For clarification, this does not include manufacturing operations documentation (i.e. batch production records, sampling plans, raw material specifications, media prep documents).
- Review of applicable change controls related to the facility and program for regulatory impact.
- Module 2 and Module 3 Quality CMC technical writing resulting in WORD CTD deliverables, supporting two complete rounds of review per document.

CMC consultation and guidance shall be limited to products manufactured in ADM Facility or by ADM subcontractors specific to this project.

Section 3-Project Schedule: Section 3 of PAII shall be amended to include Task 9, listed below:

Task	Description	Start	End
9	Regulatory Support	November 2021	TBD

Section 4, Project Budget: Section 4 of PA II shall be amended to include the budget for Task 9, by adding the following language:

The budget for Task 9 is **$300,000.**

Section 5, Payment Schedule: Section 5 of PA II shall be amended to include the Payment Schedule for Task 9 by adding the following language:

Milestone	Description	Price
23	Initiation of Task 9: Regulatory Support (50%)	$ 150,000
24	Completion of Task 9: Regulatory Support (50%)	$ 150,000

Payment Terms

Ology Bio will invoice Client in the amounts and as provided in the Payment Schedule above. Payment is due in accordance with Section 6.4 of the MSA.

Section 9, General Assumptions: Section 9 of PA II shall be amended to include the following language:

13. The schedules, estimates and costs contained within this Project Addendum are subject to the General Assumptions set forth in PA II.

PA II Terms:

This Amendment 1 is intended to supplement the scope of work set forth in PA II. Except as expressly provided in this Amendment, all of the terms, conditions and general assumptions set forth in PA II remain in full force and effect.

(Signature Page Follows)

IN WITNESS WHEREOF, the Parties have caused this Amendment to be executed by their duly authorized representatives.

Ology Bioservices, Inc.

By: /s/ Todd Ranheim

Name: Todd Ranheim

Title: Head, Analytical Science & Technology

Date: 4/26/2022

Blue Water Vaccines, Inc.

By: /s/ Joe Hernandez

Name: Joe Hernandez

Title: CEO

Date: 4/19/2022

Exhibit 10.2

EXCLUSIVE LICENSE AGREEMENT
AMENDMENT #1

This Amendment ("Amendment"), effective as of May 11, 2022 (Effective Date), amends that certain Exclusive License Agreement of January 27, 2020 by and between **Blue Water Vaccines, Inc.** (Company) and **St. Jude Children's Research Hospital, Inc.** (St. Jude) (the "License Agreement").

WHEREAS the parties wish to revise the term of the License Agreement to include the inventions disclosed in provisional patent application number 63/329,083, filed April 8, 2022, titled "Vaccine Compositions and Methods for Reducing Transmission of Pathogens" (St. Jude File No. SJ-22-0020), developed by St. Jude;

NOW THEREFORE, in consideration of the above, the Parties agree that the following terms will apply.

Article 1.9 shall be revised to read:

1.9 "PATENT RIGHTS" shall mean U.S. provisional patent application no. 61/537,290, titled "Live, Attenuated Streptococcus Pneumoniae Strain and Vaccine for Protection Against Pneumococcal Disease" filed on September 21, 2011, which issued as US patent number 9,265,819 on February 23, 2016 and U.S. provisional patent application no. 62/817,748 filed March 13, 2019 and U.S. provisional patent application no. 63/329,083 titled "Vaccine Compositions and Methods for Reducing Transmission of Pathogens" filed April 8, 2022 owned by LICENSOR and all invention(s) disclosed and claimed therein ("INVENTION"), and any issued patents, divisions, continuations, continuations-in-part to the extent that the claims are directed to subject matter described in the above-referenced patent applications and are entitled to the priority date of the existing PATENT RIGHTS, reexaminations, substitutions, renewals, restorations, additions or registrations thereof, as well as non-United States counterparts thereof and extensions and supplementary protection certificates thereon.

EXHIBIT A shall be revised to read:

EXHIBIT A

LICENSE FEE & ROYALTIES

1. **License Fee:** The initial license fee due under Paragraph 3.1 within thirty (30) days of the EFFECTIVE DATE is fifteen thousand US dollars ($15,000). A first amendment fee of five thousand US dollars ($5,000) is due within thirty (30) days of the Effective Date of this Amendment #1.

2. **Annual Maintenance Fee:** The annual maintenance fee pursuant to Paragraph 3.2 is ten thousand US dollars ($10,000) per year, beginning on the first anniversary of the effective date of the license.

3. **Royalties:** The running royalty rate payable under Paragraph 3.3 is five percent (5%).

   In the event COMPANY is required to enter into one or more third party license agreements to practice Patent Rights, the royalty payments due LICENSOR may be reduced by a percentage equal to half of that paid to such third party. However, in no event shall the milestone payments due to LICENSOR be reduced by more than one half of the original royalty percentage.

SUBLICENSE CONSIDERATION: COMPANY shall pay LICENSOR Fifteen percent (15%) of any SUBLICENSE CONSIDERATION.

EXHIBIT B shall be revised to read:

EXHIBIT B

DEVELOPMENTAL MILESTONES & MILESTONE PAYMENTS

1. **Developmental Milestones:** Developmental Milestones by COMPANY for a LICENSED PRODUCT in accord with Paragraph 5.3 are as follows:

Complete IND enabling study	2022/2023
Initiate animal toxicology study	last half 2022
File IND	last half 2023
Complete PHASE I CLINICAL TRIAL	last half of 2024
Commence PHASE II CLINICAL TRIAL	2025
Commence PHASE III CLINICAL TRIAL	2027
Regulatory approval, US or foreign equivalent	2030-2032

2. **Milestone Payments:** The Milestone Payments payable under Paragraph 3.5 are as follows:

Upon Commencement of PHASE III CLINICAL TRIAL	$	300,000
Upon regulatory approval, US or foreign equivalent	$	600,000
Upon FIRST COMMERCIAL SALE	$	1,000,000

"Commence" or "Commencement" of either a PHASE I, PHASE II or PHASE III CLINCIAL TRIAL shall mean the dosing of the first patient in such PHASE I, PHASE II, or PHASE III CLINICAL TRIAL.

All other terms and conditions of the original Exclusive License Agreement shall remain in full force and effect.

IN WITNESS WHEREOF, the parties have caused this Amendment to be duly executed as of the date first set forth above by their respective duly authorized offices.

BLUE WATER VACCINES, INC.

/s/ Joseph Hernandez Date 5/10/2022

Name: Joseph Hernandez
Title: Chief Executive Officer

ST. JUDE CHILDREN'S RESEARCH HOSPITAL, INC.

/s/ J. Scott Elmer Date

J. Scott Elmer
Director, Technology Licensing

Exhibit 31.1

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 March 31, 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: May 13, 2022

/s/ Joseph Hernandez
Joseph Hernandez
Chief Executive Officer

Exhibit 31.2

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 March 31, 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: May 13, 2022

/s/ Jon Garfield
Jon Garfield
Chief Financial Officer

Exhibit 32.1

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 March 31, 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: May 13, 2022

/s/ Joseph Hernandez
Joseph Hernandez,
Chief Executive Officer

Exhibit 32.2

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 March 31, 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: May 13, 2022

/s/ Jon Garfield
Jon Garfield,
Chief Financial Officer