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, 2023

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 Biotech, 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

Blue Water Vaccines Inc.
(Former name, former address and former fiscal year, if changed since last report)

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, 2023, the registrant had 15,905,732 shares of common stock, $0.00001 par value per share, outstanding.

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CAUTIONARY NOTE REGARDING FORWARD-LOOKING STATEMENTS

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

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

- our projected financial position and estimated cash burn rate;
- our estimates regarding expenses, future revenues and capital requirements;
- our ability to continue as a going concern;
- our need to raise substantial additional capital to fund our operations;
- the success, cost and timing of our clinical trials;
- our ability to obtain the necessary regulatory approvals to market and commercialize our products and 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, including manufacturers and logistics companies;
- the success of competing therapies and products that are or become available;
- our ability to commercialize ENTADFI®;
- our ability to successfully compete against current and future competitors;
- 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 products and 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 BIOTECH, INC.
Condensed Balance Sheets

	March 31, 2023 (Unaudited)	December 31, 2022
ASSETS		
Current assets		
Cash	$ 20,255,803	$ 25,752,659
Restricted cash	1,000,000	—
Prepaid expenses and other current assets	780,173	469,232
Deferred offering costs	366,113	—
Receivable from related parties	70,302	35,850
Total current assets	22,472,391	26,257,741
Prepaid expenses, long-term	15,500	38,617
Property and equipment, net	14,210	14,089
Total assets	**$ 22,502,101**	**$ 26,310,447**
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities		
Accounts payable	$ 1,503,262	$ 1,499,296
Accrued expenses	1,292,951	2,409,128
Contingent warrant liability	12,406	14,021
Total current liabilities	2,808,619	3,922,445
Total liabilities	**2,808,619**	**3,922,445**
Commitments and Contingencies (see Note 7)		
Stockholders' equity		
Preferred stock, $0.00001 par value, 10,000,000 shares authorized at March 31, 2023 and December 31, 2022; 0 shares issued and outstanding at March 31, 2023 and December 31, 2022	—	—
Common stock, $0.00001 par value, 250,000,000 shares authorized at March 31, 2023 and December 31, 2022; 16,371,597 and 15,724,957 shares issued at March 31, 2023 and December 31, 2022, respectively; 15,879,230 and 15,265,228 shares outstanding at March 31, 2023 and December 31, 2022, respectively	164	157
Additional paid-in-capital	42,516,726	42,331,155
Treasury stock, at cost; 492,367 and 459,729 shares of common stock at March 31, 2023 and December 31, 2022, respectively	(600,264)	(566,810)
Accumulated deficit	(22,223,144)	(19,376,500)
Total stockholders' equity	19,693,482	22,388,002
Total liabilities and stockholders' equity	**$ 22,502,101**	**$ 26,310,447**

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

BLUE WATER BIOTECH, INC.
Condensed Statements of Operations
(Unaudited)

	Three Months Ended March 31, 2023	Three Months Ended March 31, 2022
Operating expenses		
General and administrative	$ 1,766,022	$ 1,615,569
Research and development	1,082,237	455,092
Total operating expenses	2,848,259	2,070,661
Loss from operations	(2,848,259)	(2,070,661)
Other income		
Change in fair value of contingent warrant liability	(1,615)	—
Total other income	(1,615)	—
Net loss	**$ (2,846,644)**	**$ (2,070,661)**
Cumulative preferred stock dividends	—	96,359
Net loss applicable to common stockholders	(2,846,644)	(2,167,020)
Net loss per share attributable to common stockholders, basic and diluted	$ (0.18)	$ (0.34)
Weighted average number of common shares outstanding, basic and diluted	15,910,415	6,339,435

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

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

	Preferred Stock		Common Stock		Additional Paid-in Capital	Treasury Stock		Accumulated Deficit	Total Stockholders' Equity
	Shares	Amount	Shares	Amount		Shares	Amount		
Balance at December 31, 2022	—	$ —	**15,724,957**	**$ 157**	**$42,331,155**	**(459,729)**	**$ (566,810)**	**$ (19,376,500)**	**$ 22,388,002**
Exercise of pre-funded warrants	—	—	646,640	7	(7)	—	—	—	—
Stock-based compensation	—	—	—	—	185,578	—	—	—	185,578
Purchase of treasury shares	—	—	—	—	—	(32,638)	(33,454)	—	(33,454)
Net loss	—	—	—	—	—	—	—	(2,846,644)	(2,846,644)
Balance at March 31, 2023	—	$ —	**16,371,597**	**$ 164**	**$42,516,726**	**(492,367)**	**$ (600,264)**	**(22,223,144)**	**$ 19,693,482**

	Preferred Stock		Common Stock		Additional Paid-in Capital	Treasury Stock		Accumulated Deficit	Total Stockholders' Equity
	Shares	Amount	Shares	Amount		Shares	Amount		
Balance at December 31, 2021	**1,146,138**	**$ 11**	**3,200,000**	**$ 32**	**$ 7,403,204**	**—**	$ —	**$ (5,956,670)**	**$ 1,446,577**
Issuance of common stock in initial public offering, net of $2.9 million of offering costs	—	—	2,222,222	22	17,138,818	—	—	—	17,138,840
Conversion of convertible preferred stock to common stock upon initial public offering	(1,146,138)	(11)	5,626,365	56	(45)	—	—	—	—
Stock-based compensation	—	—	—	—	19,322	—	—	—	19,322
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**

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

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

	Three Months Ended March 31, 2023	Three Months Ended March 31, 2022
Cash flows from operating activities		
Net loss	$ (2,846,644)	$ (2,070,661)
Adjustments to reconcile net loss to net cash used in operating activities:		
Stock-based compensation	185,578	19,332
Depreciation expense	1,698	1,300
Change in fair value of contingent warrant liability	(1,615)	—
Changes in assets and liabilities:		
Prepaid expenses and other current assets	(321,961)	144,546
Receivable from related parties	(34,452)	(11,991)
Prepaid expenses, long-term	23,117	(129,454)
Deposit	—	(87,638)
Accrued expenses	(1,237,493)	896,659
Accounts payable	(214,311)	351,816
Net cash used in operating activities	(4,446,083)	(886,091)
Cash flows from investing activities		
Purchase of property and equipment	(1,819)	(5,197)
Net cash used in investing activities	(1,819)	(5,197)
Cash flows from financing activities		
Purchase of treasury shares	(33,454)	—
Payment of deferred offering costs	(15,500)	(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 (used in) financing activities	(48,954)	17,572,063
Net increase (decrease) in cash and restricted cash	(4,496,856)	16,680,775
Cash and restricted cash, beginning of period	25,752,659	1,928,474
Cash and restricted cash, end of period	$ 21,255,803	$ 18,609,249
Noncash investing and financing activities:		
Deferred offering costs included in accounts payable and accrued expenses	$ 339,593	$ 233,804
Deferred offering costs previously prepaid	$ (11,020)	$ —
Exercise of pre-funded warrants	$ 7	$ —
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 BIOTECH, INC.
Notes to Condensed Financial Statements
(Unaudited)

Note 1 — Organization and Basis of Presentation

Organization and Nature of Operations

Blue Water Biotech, Inc. (formerly 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 candidate, BWV-201, is a live attenuated, intranasally delivered, serotype independent Streptococcus pneumoniae vaccine targeting S. pneumo-induced acute otitis media and pneumococcal pneumonia. BWV's influenza vaccine candidates, BWV-101 and BWV-102, are being investigated as a universal influenza vaccine with the potential to protect against all influenza strains and a pre-pandemic H1 influenza vaccine, respectively. In addition to exploratory analysis for applications in flu vaccines, the Company's virus-like particle platform is being utilized to investigate and develop vaccine candidates against norovirus, rotavirus, malaria, monkeypox, and Marburg virus disease. Finally, the Company is developing a live attenuated, orally delivered Chlamydia vaccine. All of the Company's vaccine candidates are in the pre-clinical developmental stage. In addition, in April 2023, the Company acquired ENTADFI®, with plans to commercialize it. ENTADFI® is an FDA-approved, once daily pill that combines finasteride and tadalafil for the treatment of benign prostatic hyperplasia. This combination allows men to receive treatment for their symptoms of benign prostatic hyperplasia without the negative sexual side effects typically seen in patients on finasteride alone.

Effective April 21, 2023, the Company changed its corporate name from "Blue Water Vaccines Inc." to "Blue Water Biotech, Inc." See Note 11.

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, par value $0.00001 per share ("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 the Company's convertible preferred stock were converted into 5,626,365 shares of common stock.

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").

Unaudited Interim Financial Statements

The accompanying condensed balance sheet as of March 31, 2023, 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, 2023 and 2022 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, 2023 and its results of operations and cash flows for the three months ended March 31, 2023 and 2022. 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, 2023 are not necessarily indicative of the results that may be expected for the year ending December 31, 2023, any other interim periods, or any future year or period. The unaudited condensed financial statements included in this Report 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, 2022, which includes a broader discussion of the Company's business and the risks inherent therein.

Note 2 — Going Concern and Management's Plans

The Company's operating activities to date 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 from its IPO and private placement issuances in April and August 2022 (the "Private Placements"), see Note 6. During 2022, the Company completed its IPO and the Private Placements in which the Company received an aggregate of approximately $33.1 million in net cash proceeds, after deducting placement agent fees and other offering expenses.

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, 2023, the Company had cash of approximately $20.3 million, working capital of approximately $19.7 million and an accumulated deficit of approximately $22.2 million. During April 2023, the Company completed an acquisition of assets that requires the Company to pay initial consideration of $20.0 million, of which $6.0 million was paid upon close, and $9.0 million of the remainder is due to the seller of the assets within one year of the date these condensed financial statements were issued. The remaining $5.0 million is due in September 2024. See Note 11.

These factors, along with the Company's forecasted future cash flows, indicate that the Company will be unable to meet its contractual commitments and obligations as they come due in the ordinary course of business within one year following the issuance of these condensed financial statements. The Company will require significant additional capital to fund its continuing operations, satisfy existing and future obligations and liabilities, and otherwise support the Company's working capital needs and business activities, including the commercialization of ENTADFI® and the development and commercialization of its current product candidates and future product candidates. Management's plans include generating product revenue from sales of ENTADFI®, which is subject to successful commercialization activities, some of which are outside of the Company's control, including but not limited to, securing contracts with wholesalers and third party payers, securing contracts with third-party logistics providers, obtaining required licensure in various jurisdictions, and building a salesforce, as well as attempting to secure additional required funding through equity or debt financings if available; 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, development and/or commercialization of products and product candidates, and it may take additional measures to reduce expenses in order to conserve its cash in amounts sufficient to sustain operations and meet its obligations.

Because of historical and expected operating losses and net operating cash flow deficits, there is substantial doubt about the Company's ability to continue as a going concern for one year from the issuance of the condensed financial statements, which is not alleviated by management's plans. The condensed financial statements have been prepared assuming the Company will continue as a going concern. These condensed financial statements do not include any adjustments that might be necessary from the outcome of this uncertainty.

Note 3 — Summary of Significant Accounting Policies

During the three months ended March 31, 2023, there were no changes to the Company's significant accounting policies as described in the Company's Annual Report on Form 10-K for the year ended December 31, 2022, except for the following:

Restricted Cash

Restricted cash maintained under agreements that legally restrict the use of such funds is not included with cash and is reported as a separate line item on the condensed balance sheet. Restricted cash as of March 31, 2023, primarily consists of earnest money deposited in a financial institution for a potential asset acquisition. Subsequent to March 31, 2023, the funds were released from escrow to the Company and reclassified from restricted cash to cash.

A reconciliation of the Company's cash and restricted cash in the condensed balance sheet to cash and restricted cash in the condensed statement of cash flows as of March 31, 2023 and is as follows:

	As of March 31, 2023	As of December 31, 2022
Cash	$ 20,255,803	$ 25,752,659
Restricted cash	1,000,000	—
Cash and restricted cash	**$ 21,255,803**	**$ 25,752,659**

New Accounting Pronouncements

The Company's management does not believe that any 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 and Other Current Assets

Prepaid expenses and other current assets consisted of the following as of March 31, 2023 and December 31, 2022:

	As of March 31, 2023	As of December 31, 2022
Prepaid research and development	$ 208,583	$ 231,981
Prepaid insurance	484,788	148,789
Prepaid other	86,802	88,462
Total	**$ 780,173**	**$ 469,232**

Accrued Expenses

Accrued expenses consisted of the following as of March 31, 2023 and December 31, 2022:

	As of March 31, 2023	As of December 31, 2022
Accrued license fees	$ —	$ 15,000
Accrued research and development	549,762	847,747
Accrued deferred offering costs	246,316	125,000
Accrued compensation	324,051	1,132,859
Accrued franchise taxes	26,200	177,600
Accrued director fees	109,375	38,750
Accrued other	37,247	72,172
Total	**$ 1,292,951**	**$ 2,409,128**

Note 5 — Significant Agreements

Oxford University Innovation Limited

In December 2018, the Company entered into an option agreement with Oxford University Innovation ("OUI"), which was a precursor to a license agreement (the "OUI Agreement"), dated July 16, 2019. Under the terms of the OUI Agreement, the Company holds an exclusive, worldwide license to certain specified patent rights and biological materials relating to the use of epitopes of limited variability and virus-like particle products and practice processes that are covered by the licensed patent rights and biological materials for the purpose of developing and commercializing a vaccine product candidate for influenza. The Company is obligated to use its best efforts to develop and market Licensed Products, as defined in the OUI Agreement, in accordance with its development plan, report to OUI on progress, achieve the following milestones and must pay OUI nonrefundable milestone fees when it achieves them: initiation of first Phase I study; initiation of first Phase II study; initiation of first Phase III/pivotal registration studies; first submission of application for regulatory approval (BLA/NDA); marketing authorization in the United States; marketing authorization in any EU country; marketing authorization in Japan; first marketing authorization in any other country; first commercial sale in Japan; first commercial sale in any ROW country; first year that annual sales equal or exceed certain thresholds. The OUI Agreement also requires the Company to pay certain milestone and royalty payments in the future, as the related contingent events occur. 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, 2023. Either party may terminate the OUI Agreement for an uncured material breach. The Company was able to terminate the OUI Agreement for any reason at any time upon six months' written notice until July 16, 2022, which was the third anniversary of the OUI Agreement. OUI may terminate immediately if the Company has a petition presented for its winding-up or passes a resolution for winding up other than for a bona fide amalgamation or reconstruction or compounds with its creditors or has a receiver or administrator appointed. OUI may also terminate if the Company opposes or challenges the validity of any of the patents or applications in the Licensed Technology, as defined in the OUI Agreement; raises the claim that the know-how of the Licensed Technology is not necessary to develop and market Licensed Products; or in OUI's reasonable opinion, is taking inadequate or insufficient steps to develop or market Licensed Products and does not take any further steps that OUI requests by written notice within a reasonable time.

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 requires the Company to pay certain milestone and royalty payments in the future, as the related contingent events occur. The St. Jude Agreement will expire upon the expiration of the last valid claim contained in the licensed patent rights, unless terminated earlier. The Company is obligated to use commercially reasonable efforts to develop and commercialize the licensed product(s). The milestones include the following events: (i) complete IND enabling study; (ii) initiate animal toxicology study; (iii) file IND; (iv) complete Phase I Clinical Trial; (v) commence Phase II Clinical Trial; (vi) commence Phase III Clinical Trial; and, (vii) regulatory approval, U.S. or foreign equivalent. If the Company fails to achieve the development milestones contained in the St. Jude Agreement, and if the Company and St. Jude fail to agree upon a mutually satisfactory revised timeline, St. Jude will have the right to terminate the St. Jude Agreement. Either party may terminate the St. Jude Agreement in the event the other party (a) files or has filed against it a petition under the Bankruptcy Act (among other things) or (b) fails to perform or otherwise breaches its obligations under the St. Jude Agreement, and has not cured such failure or breach within sixty (60) days. The Company may terminate for any reason on thirty (30) days written notice. On May 11, 2022, the Company entered into an amendment to the St. Jude Agreement, whereby the royalty terms, milestone payments and licensing fees were amended, and a revised development milestone timeline was agreed to. On March 22, 2023, the Company entered into another amendment to the St. Jude Agreement, whereby the development milestone timeline was further revised and which had no financial impact.

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 agreed upon development milestone payments and royalty payment to CHMC, as the related contingent events occur. The Company may terminate the CHMC Agreement for convenience, at any time prior to first commercial sale of a product or process by providing one hundred and eighty (180) days' written notice to CHMC. It may also terminate for a CHMC uncured material breach. CHMC may terminate the CHMC Agreement for an uncured Company material breach or insolvency or bankruptcy. Pursuant to the terms of the CHMC Agreement, if the Company fails to achieve the milestones, and cannot mutually agree with CHMC on an amendment to the milestones, then CHMC will have the option of converting any and all of such exclusive licenses to nonexclusive licenses, to continue developing indications that have already entered development at any stage or in which the Company has invested in developing. CHMC may also terminate the CHMC Agreement to the fullest extent permitted by law in the countries of the worldwide territory, in the event the Company or its affiliates challenge or induce others set up challenges to the validity or enforceability of any of the Licensed Patents, as defined in the CHMC Agreement, and the Company will be obligated to reimburse CHMC for its costs, including reasonable attorneys' fees.

Note 5 — Significant Agreements (cont.)

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 December 31, 2022. 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, at which point the Company had paid Ology $100,000 for services to be provided. 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%.

During 2022, the Company entered into three amendments to the Ology MSA to adjust the scope of work defined in the second Project Addendum. The amendments resulted in a net increase to the Company's obligations under the second Project Addendum of $154,000. On March 27, 2023, the second Project Addendum to the Ology MSA was further amended to increase the scope of the project, resulting in an increase to the Company's obligations of $180,000 under the Ology MSA.

During the three months ended March 31, 2023 the Company incurred related research and development expenses of approximately $335,000, and at March 31, 2023, the Company had approximately $734,000 and $271,000 recorded as related accounts payable and accrued expenses, respectively. There was approximately $217,000 of related expenses incurred during the three months ended March 31, 2022.

University of Texas Health Science Center at San Antonio

The Company entered into a patent and technology license agreement (the "UT Health Agreement"), dated November 18, 2022, with the University of Texas Health Science Center at San Antonio ("UT Health"). Under the terms of the UT Health Agreement, the Company holds an exclusive, worldwide license (other than the excluded field of vectors, as defined in the UT Health Agreement) to certain specified patent rights relating to the development of a live attenuated, oral Chlamydia vaccine candidate. An initial non-refundable license fee of $100,000 was due upon execution of the agreement and subsequent annual license fees are due as follows: $20,000 per year for each of the four years ending on December 31, 2026; $40,000 per year for each of the two years ending on December 31, 2028, and $60,000 per year for the year ending December 31, 2029 and each year thereafter until expiration or termination of the UT Health agreement. The UT Health Agreement also requires the Company to pay certain milestone and royalty payments in the future, as the related contingent events occur. The UT Health Agreement will expire upon the expiration of the last date of expiration or termination of the patent rights, unless terminated earlier. The Company may terminate the UT Health Agreement for convenience, by providing 90 days' written notice to UT Health. UT Health may terminate the UT Health Agreement in the event the Company (a) becomes arrears in payment due and does not make payment within 30 days after notification from UT Health or (b) is in breach of any non-payment provision and does not cure such breach within 60 days after notification from UT Health or (c) UT Health delivers notice to the Company of three or more actual material breaches of the UT Health Agreement in any 12-month period or (d) in the event the Company or its affiliates initiates any proceeding or action to challenge the validity, enforceability, or scope of any of the licensed patents.

Co-development Agreement with AbVacc, Inc.

On February 1, 2023, the Company entered into a co-development agreement (the "Co-Development Agreement") with AbVacc, Inc. ("AbVacc"), for the purpose of conducting research aimed at co-development of specific vaccine candidates, including monkeypox and Marburg virus disease with the potential to expand to others using the Norovirus nanoparticle platform ("Co-Development Project"), and to govern the sharing of materials and information, as defined in the Co-Development Agreement, for the Co-Development Project. Under the Co-Development Agreement, AbVacc and the Company will collaborate, through a joint development committee, to establish and implement a development plan or statement of work for each Co-Development Project targeted product. Under the Co-Development Agreement, either the Company or AbVacc, whichever party is the primary sponsor of any resulting product (as defined in the Co-Development Agreement), will be obligated to compensate the other party for certain milestone payments that would range between $2.1 million and $4.75 million, plus royalties of between 2% to 4%. There is no fixed obligation for either party, and each party will be responsible for their own costs. The term of the Co-Development Agreement is three years from the effective date, unless previously terminated by either party, in accordance with the Co-Development Agreement. During the three months ended March 31, 2023, the Company incurred approximately $8,000 in costs for research and development related to the Co-Development Agreement. As of March 31, 2023, the Company evaluated the likelihood of the Company achieving the specified milestones and generating product sales, and determined that the likelihood is not yet probable and as such no accrual of these payments is required as of March 31, 2023.

Note 6 — Stockholders' Equity

Authorized Capital

On February 23, 2022, in connection with the closing of the IPO, the Company filed with the Secretary of State of the State of Delaware its second amended and restated certificate of incorporation (the "A&R COI"), which became effective immediately. 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.

Common Stock

As of March 31, 2023 and December 31, 2022, there were 16,371,597 and 15,724,957 shares of common stock issued, respectively, and 15,879,230 and 15,265,228 shares of common stock 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. 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.

Treasury Stock

On November 10, 2022, the board of directors of the Company (the "Board") approved a stock repurchase program (the "Repurchase Program") to allow the Company to repurchase up to 5.0 million shares of common stock with a maximum price of $1.00 per share, with discretion to management to make purchases subject to market conditions. On November 18, 2022, the Board approved an increase to the maximum price to $2.00 per share. There is no expiration date for this program.

During the three months ended March 31, 2023, the Company repurchased 32,638 shares of common stock at an average price of $1.03 per share, for an aggregate of approximately $33,500. Shares that are repurchased are classified as treasury stock pending future use and reduce the number of shares outstanding used in calculating earnings per share. As of March 31, 2023, there are approximately 4.5 million shares remaining, that can be repurchased under the Repurchase Program.

Private Investments in Public Equity

April Private Placement

On April 19, 2022, the Company consummated the closing of a private placement (the "April Private Placement"), pursuant to the terms and conditions of a securities purchase agreement, dated as of April 13, 2022. At the closing of the April Private Placement, the Company issued 590,406 shares of common stock, pre-funded warrants to purchase an aggregate of 590,406 shares of common stock and preferred investment options to purchase up to an aggregate of 1,180,812 shares of common stock. The purchase price of each share of common stock together with the associated preferred investment option was $6.775, and the purchase price of each pre-funded warrant together with the associated preferred investment option was $6.774. The aggregate net cash proceeds to the Company from the April Private Placement were approximately $6.9 million, after deducting placement agent fees and other offering expenses. The pre-funded warrants had an exercise price of $0.001 per share and were exercised in full on May 24, 2022. The preferred investment options, which had an exercise price of $6.65 per share, were exchanged in connection with the August Private Placement, as discussed below.

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

Note 6 — Stockholders' Equity (cont.)

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

The Company evaluated the terms of the April Contingent Warrants and determined that they should be classified as a liability based upon accounting guidance provided in ASC 815-40. Since the April Contingent Warrants are a form of compensation to Wainwright, the Company recorded the value of the liability as a reduction of additional paid in capital, with subsequent changes in the value of the liability recorded in other income in the accompanying statements of operations.

August Private Placement

On August 11, 2022, the Company consummated the closing of a private placement (the "August Private Placement"), pursuant to the terms and conditions of a securities purchase agreement, dated as of August 9, 2022. At the closing of the August Private Placement, the Company issued 1,350,000 shares of common stock, pre-funded warrants to purchase an aggregate of 2,333,280 shares of common stock and preferred investment options to purchase up to an aggregate of 4,972,428 shares of common stock. The purchase price of each share of common stock together with the associated preferred investment option was $2.715, and the purchase price of each pre-funded warrant together with the associated preferred investment option was $2.714. The aggregate net cash proceeds to the Company from the August Private Placement were approximately $8.7 million, after deducting placement agent fees and other offering expenses. In addition, the investors in the August Private Placement, who are the same investors from the April Private Placement, agreed to cancel preferred investment options to purchase up to an aggregate of 1,180,812 shares of the Company's common stock issued in April 2022. The pre-funded warrants had an exercise price of $0.001 per share. During 2022, an aggregate of 1,686,640 of the pre-funded warrants were exercised. The remaining 646,640 of pre-funded warrants were exercised during the three months ended March 31, 2023. The preferred investment options are exercisable at any time on or after August 11, 2022 through August 12, 2027, at an exercise price of $2.546 per share, subject to certain adjustments as defined in the agreement. No preferred investment options have been exercised as of March 31, 2023.

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

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

The investors in the April Private Placement agreed to cancel the aggregate of 1,180,812 preferred investment options issued in the April Private Placement, as part of their participation in the August Private Placement. The preferred investment options that were cancelled were effectively exchanged for 1,289,148 new preferred investment options in the August Private Placement, and accordingly have been accounted for as a modification or exchange of equity-linked instruments. In accordance with ASC 815-40, as the preferred investment options were classified as equity instruments before and after the exchange, and as the exchange is directly attributable to an equity offering, the Company recognized the effect of the exchange as an equity issuance cost.

The Company evaluated the terms of the August Contingent Warrants and determined that they should be classified as a liability based upon accounting guidance provided in ASC 815-40. As a result of the exchange of the preferred investment options issued in the April Private Placement, the underlying equity-linked instruments that would trigger issuance of the April Contingent Warrants was replaced, and therefore the 70,849 of April Contingent Warrants were exchanged for 70,849 of the August Contingent Warrants. The value of the April Contingent Warrant liability was adjusted to fair value on the date of modification, using a Monte Carlo simulation, with the change in fair value recognized in the accompanying statements of operations. The remaining 227,497 August Contingent Warrants were measured as a liability upon the close of the August Private Placement. Since the Contingent Warrants are a form of compensation to the placement agent, the Company recorded the value of the liability as a reduction of additional paid in capital.

Note 6 — Stockholders' Equity (cont.)

At the Market Offering Agreement

On March 29, 2023, the Company entered into an At The Market Offering Agreement (the "ATM Agreement") with H.C. Wainwright & Co., LLC, as sales agent (the "Agent"), to create an at-the-market equity program under which it may sell up to $3,900,000 of shares of the Company's common stock (the "Shares") from time to time through the Agent (the "ATM Offering"). Under the ATM Agreement, the Agent will be entitled to a commission at a fixed rate of 3.0% of the gross proceeds from each sale of Shares under the ATM Agreement.

Sales of the Shares, if any, under the ATM Agreement may be made in transactions that are deemed to be "at-the-market equity offerings" as defined in Rule 415 under the Securities Act of 1933, as amended (the "Securities Act"), including sales made by means of ordinary brokers' transactions, including on the Nasdaq Capital Market, at prevailing market prices at the time of sale or as otherwise agreed with the Agent. The Company has no obligation to sell, and the Agent is not obligated to buy or sell, any of the Shares under the Agreement and may at any time suspend offers under the Agreement or terminate the Agreement. The ATM Offering will terminate upon the termination of the ATM Agreement as permitted therein.

The Shares will be issued pursuant to the Company's previously filed Registration Statement on Form S-3 (File No. 333-270383) that was declared effective on March 16, 2023 and a prospectus supplement and accompanying prospectus relating to the ATM Offering filed with the with the Securities and Exchange Commission ("SEC") on March 29, 2023.

Deferred offering costs associated with the ATM Agreement are reclassified to additional paid in capital on a pro-rata basis when the Company completes offerings under the ATM Agreement. Any remaining deferred costs will be expensed to the statements of operations should the planned offering be abandoned.

As of March 31, 2023, no shares have been sold under the ATM Offering.

Warrants

The following summarizes activity related to the Company's outstanding warrants, excluding contingent warrants issuable upon exercise of the preferred investment options, for the three months ended March 31, 2023:

	Number of Shares	Weighted Average Exercise Price	Weighted Average Remaining Contractual Life (in years)
Outstanding as of December 31, 2022	5,910,914	$ 2.37	4.7
Granted	—	—	
Exercised	(646,640)	0.001	
Cancelled	—	—	
Outstanding as of March 31, 2023	5,264,274	2.66	4.4
Warrants vested and exercisable as of March 31, 2023	5,264,274	$ 2.66	4.4

As of March 31, 2023, the outstanding warrants include 70,849 April Private Placement Warrants and 5,193,425 August Private Placement Warrants, which are exercisable into 5,264,274 shares of common stock which had a fair value of $1.07 per share, based on the closing trading price on that day.

Additionally, as of March 31, 2023 and December 31, 2022, the value of the April Contingent Warrants and the August Contingent Warrants (collectively the "Contingent Warrants") was approximately $12,000 and $14,000, respectively, and none of the Contingent Warrants have been issued, as no preferred investment options have been exercised.

Equity Incentive Plans

The Company's 2019 Equity Incentive Plan (the "2019 Plan") was adopted by the Board 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, 2023 and 2022.

Note 6 — Stockholders' Equity (cont.)

In addition, on February 23, 2022 and in connection with the closing of the IPO, the Board adopted the Company's 2022 Equity Incentive Plan (the "2022 Plan"), which is the successor and continuation of the Company's 2019 Plan. Under the 2022 Plan, the Company may grant stock options, restricted stock, restricted stock units, stock appreciation rights, and other forms of awards to employees, directors and consultants of the Company. Upon its effectiveness, a total of 1,600,000 shares of common stock were reserved for issuance under the 2022 Plan. In August 2022, the number of shares of common stock reserved for issuance under the 2022 Plan was increased to 2,600,000. The stock options granted during the three months ended March 31, 2023 were all granted under the 2022 Plan. As of March 31, 2023, there are 965,446 options available for issuance under the 2022 Plan.

Stock Options

The following summarizes activity related to the Company's stock options under the 2019 Plan and the 2022 Plan for the three months ended March 31, 2023:

	Number of Shares	Weighted Average Exercise Price	Total Intrinsic Value	Weighted Average Remaining Contractual Life (in years)
Outstanding as of December 31, 2022	1,392,654	$ 3.30	$ 670,161	8.2
Granted	102,386	1.19	—	—
Forfeited / cancelled	(25,938)	2.65	—	—
Exercised	—	—	—	—
Outstanding as of March 31, 2023	1,469,102	3.17	$ 635,147	8.1
Options vested and exercisable as of March 31, 2023	1,024,322	$ 2.87	$ 557,559	7.7

The fair value of options granted in 2023 was estimated using the following assumptions:

	For the Three Months Ended March 31, 2023
Exercise price	$ 1.05 – 1.29
Term (years)	5.00 – 10.00
Expected stock price volatility	113.1% – 119.5%
Risk-free rate of interest	3.5% – 3.6%

The weighted average grant date fair value of stock options granted during the three months ended March 31, 2023 was $1.08. The aggregate fair value of stock options that vested during the three months ended March 31, 2023 was approximately $272,000.

Stock-Based Compensation

Stock-based compensation expense for the three months ended March 31, 2023 and 2022 was as follows:

	For the Three Months Ended March 31,	
	2023	2022
General and administrative	$ 99,207	$ 6,417
Research and development	86,371	12,915
Total	**$ 185,578**	**$ 19,332**

As of March 31, 2023, unrecognized stock-based compensation expense relating to outstanding stock options is approximately $659,000, which is expected to be recognized over a weighted-average period of 1.90 years.

Note 7 — Commitments and Contingencies

Office Leases

The Company entered into a short-term lease in Palm Beach, Florida with an unrelated party, with a commencement date of May 1, 2022, for approximately $14,000 per month. The lease, which was personally guaranteed by the Company's CEO, ended on April 30, 2023. During the three months ended March 31, 2023, the Company incurred rent expense on this lease of approximately $48,000, and variable lease expense of approximately $4,000.

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, 2023, the Company is not a party to any material legal proceedings and is not aware of any pending or threatened claims.

Registration Rights Agreements

In connection with the April Private Placement (see Note 6), the Company entered into a Registration Rights Agreement with the purchasers, dated as of April 13, 2022 (the "April Registration Rights Agreement"). The April Registration Rights Agreement provides that the Company shall file a registration statement covering the resale of all of the registrable securities (as defined in the April Registration Rights Agreement) with the SEC. The registration statement on Form S-1 required under the April Registration Rights Agreement was filed with the SEC on May 3, 2022, and became effective on May 20, 2022. A post-effective amendment to the Form S-1 on Form S-3 relating to such registration statement was filed with the SEC on April 28, 2023.

In connection with the August Private Placement (see Note 6), the Company entered into a Registration Rights Agreement with the purchasers, dated as of August 9, 2022 (the "August Registration Rights Agreement"). The August Registration Rights Agreement provides that the Company shall file a registration statement covering the resale of all of the registrable securities (as defined in the August Registration Rights Agreement) with the SEC. The registration statement on Form S-1 required under the August Registration Rights Agreement was filed with the SEC on August 29, 2022, and became effective on September 19, 2022. A post-effective amendment to the Form S-1 on Form S-3 relating to such registration statement was filed with the SEC on April 28, 2023.

Upon the occurrence of any Event (as defined in the April Registration Rights Agreement and the August Registration Rights Agreement), which, among others, prohibits the purchasers from reselling the securities for more than ten consecutive calendar days or more than an aggregate of fifteen calendar days during any 12-month period, and should the registration statement cease to remain continuously effective, the Company would be 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. As of March 31, 2023, the Company determined that the likelihood of the Company incurring liquidated damages pursuant to the April Registration Rights Agreement and the August Registration Rights Agreement is remote, and as such, no accrual of these payments is required as of March 31, 2023.

Milestone and Royalty Obligations

The Company has entered into various license agreements with third parties that obligate the Company to pay certain development, regulatory, and commercial milestones, which aggregate to $115.1 million, as well as royalties based on product sales. See Note 5. As of March 31, 2023, the Company evaluated the likelihood of the Company achieving the specified milestones and generating product sales, and determined that the likelihood is not yet probable and as such no accrual of these payments is required as of March 31, 2023.

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 called for the Company to pay for consulting services performed on a monthly basis. Upon the close of the Company's IPO, the consulting agreement was terminated and the CEO's employment agreement became effective. During the three months ended March 31, 2022, the Company incurred approximately $63,000 in fees under the consulting agreement, which is recognized in general and administrative expenses in the accompanying condensed statement of operations.

During 2022 the Company entered into a lease agreement that was personally guaranteed by the Company's CEO. The lease expired on April 30, 2023. See Note 7.

During the year ended December 31, 2022, the Company's compensation committee approved one-time bonus awards of $140,000 and $100,000 to the Company's CEO and Chief Business Officer ("CBO"), respectively, in recognition of their efforts in connection with the Company's IPO. These bonuses were recognized during the three months ended March 31, 2022, as general and administrative expenses in the accompanying statements of operations.

As of March 31, 2023 and December 31, 2022, the Company has a receivable from related party of approximately $70,000 and $36,000, respectively, which consists of miscellaneous payments made by the Company on the behalf of the Company's CEO.

A former director of the Company, who currently serves on the Company's Scientific Advisory Board, 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 Board upon the close of the IPO.

Note 9 — Income Taxes

No provision for federal, state or foreign income taxes has been recorded for the three months ended March 31, 2023 and 2022. The Company has incurred net operating losses for all of the periods presented and has not reflected any benefit of such net operating loss carryforwards in the accompanying condensed financial statements due to uncertainty around utilizing these tax attributes within their respective carryforward periods. The Company has recorded a full valuation allowance against all of its deferred tax assets as it is not more likely than not that such assets will be realized in the near future. The Company's policy is to recognize interest expense and penalties related to income tax matters as income tax expense. For the three months ended March 31, 2023 and 2022, the Company has not recognized any interest or penalties related to income taxes.

Note 10 — Net Loss Per Share

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

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

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

	Three Months Ended March 31,	
	2023	**2022**
Options to purchase shares of common stock	1,469,102	780,640
Warrants	5,264,274	111,111
Total	**6,733,376**	**891,751**

Note 11 — Subsequent Events

On April 19, 2023, the Company entered into an Asset Purchase Agreement (the "APA") with Veru Inc. (the "Seller"). Pursuant to, and subject to the terms and conditions of, the APA, the Company purchased substantially all of the assets related to the Seller's ENTADFI® product ("ENTADFI®") and assumed certain liabilities of the Seller (the "Transaction") for a total possible consideration of $100 million.

In accordance with the APA, the Company agreed to provide the Seller with initial consideration totaling $20 million, consisting of (i) $6.0 million paid upon the closing of the Transaction on April 19, 2023, (ii) an additional $4.0 million in the form of a non-interest bearing note payable due on September 30, 2023, and (iii) an additional $10.0 million in the form of two $5.0 million non-interest bearing notes payable, each due on April 19, 2024 and September 30, 2024.

Additionally, the terms of the APA require the Company to pay the Seller up to an additional $80.0 million based on the Company's net sales of ENTADFI® after closing (the "Milestone Payments"). The Milestone Payments are payable as follows: (i) $10.0 million is payable upon the first time the Company achieves net sales from ENTADFI® of $100.0 million during a calendar year, (ii) $20.0 million is payable upon the first time the Company achieves net sales from ENTADFI® of $200.0 million during a calendar year, and (3) $50.0 million is payable upon the first time the Company achieves net sales from ENTADFI® of $500.0 million during a calendar year. No more than one Milestone Payment shall be made for the achievement of each net sales milestone.

In connection with the Transaction, the Company also assumed royalty and milestone obligations under an asset purchase agreement for tadalafil-finasteride combination entered into by the Seller and Camargo Pharmaceutical Services, LLC on December 11, 2017 (the "Camargo Obligations"). The Camargo Obligations assumed by the Company include a 6% royalty on all sales of tadalafil-finasteride and sales milestone payments of up to $22.5 million.

Also in connection with the Transaction, and pursuant to the APA, the Company entered into non-competition and non-solicitation agreements (the "Non-Competition Agreements") with two of the Seller's key stockholders and employees (the "Restricted Parties"). The Non-Competition Agreements generally prohibit the Restricted Parties from either directly or indirectly engaging in the Restricted Business (as such term is defined in the APA) for a period of five years from the closing of the Transaction.

The allocation of the purchase price to the underlying assets acquired and liabilities assumed is subject to a formal valuation process. Due to the limited time since the closing of the acquisition, the valuation efforts and related acquisition accounting are incomplete at the time of filing of these condensed financial statements. As a result, the Company is unable to provide amounts recognized as of the acquisition date for major classes of assets and liabilities acquired. The purchase price allocation, and other disclosures required in accordance with authoritative guidance, will be included in the quarterly report on Form 10-Q for the quarter ended June 30, 2023.

On April 21, 2023, the Company filed an amendment to its A&R COI with the Secretary of State of Delaware to change its corporate name from "Blue Water Vaccines Inc." to "Blue Water Biotech, Inc.". The name change was effective as of April 21, 2023. In connection with the name change, the Company amended the Company's bylaws to reflect the corporate name Blue Water Biotech, Inc., also effective on April 21, 2023. No other changes were made to the bylaws.

On May 9, 2023, the Company's compensation committee approved the issuance of restricted stock, granted under the Company's 2022 Plan to the Company's executive officers, employees, and certain of the Company's consultants. The restricted shares granted totaled 487,500, of which 150,000, 75,000, and 150,000 were granted to the Company's CEO, Chief Financial Officer, and CBO, respectively. All of the restricted shares granted vest as follows: 50% on August 17, 2023, 25% on August 17, 2024, and 25% on August 18, 2025.

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 Report 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, 2022, as filed with the SEC, on March 9, 2023. 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 developing transformational therapies to address significant health challenges globally. We hold exclusive, global rights to novel technology licensed from renowned research institutions around the world, including St. Jude, the University of Oxford, CHMC, and UT Health. 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. Outside of our vaccine franchise, we own ENTADFI®, an FDA-approved, once daily pill that combines finasteride and tadalafil for the treatment of benign prostatic hyperplasia ("BPH"). This combination allows men to receive treatment for their symptoms of BPH without the negative sexual side effects typically seen in patients on finasteride alone.

Since December 31, 2022, key development affecting our business include:

- ***Entered into an At The Market Offering Agreement:*** On March 29, 2023, the Company entered into the ATM Agreement with the Agent, H.C. Wainwright & Co., LLC, to create an at-the-market equity program under which it may sell up to $3,900,000 of shares of the Company's common stock from time to time through the Agent. Under the ATM Agreement, the Agent will be entitled to a commission at a fixed rate of 3.0% of the gross proceeds from each sale of shares of the Company's common stock under the ATM Agreement.

- ***Completed Acquisition of ENTADFI®, an FDA-Approved Benign Prostatic Hyperplasia Asset***: On April 19, 2023, the Company entered into the APA with Veru Inc., pursuant to which the Company purchased substantially all of the assets related to the Veru Inc.'s ENTADFI® product and assumed certain liabilities of Veru Inc. Under this agreement, the Company purchased ENTADFI® for a total consideration of up to $100 million, with $20 million paid in defined tranches through September 2024, and the possibility of an additional $80 million based on predetermined annual sales milestones.

- ***Hired Key Personnel to Support Commercial Operations and Corporate Development:*** In February 2023, the Company announced the appointment of seasoned commercial operations leader, Frank Jaeger, as Senior Vice President of Marketing and Business Development. The Company will leverage Mr. Jaeger's experience, specifically in men's health through his experience with JATENZO® and AndroGel 1.62%, in the official launch of ENTADFI® and its anticipated success within the BPH market. Also, in May 2023, the Company announced the appointment of Jay Newmark, M.D., MBA, a board-certified urologist with decades of medical and commercial Men's Health experience, as Chief Medical Officer to support the launch of ENTADFI®. Dr. Newmark's engagement with the Company will expire in June 2023, but he will support launch activities until his departure. The Company will rely heavily on Mr. Jaeger to ensure successful launch and future sales of ENTADFI®.

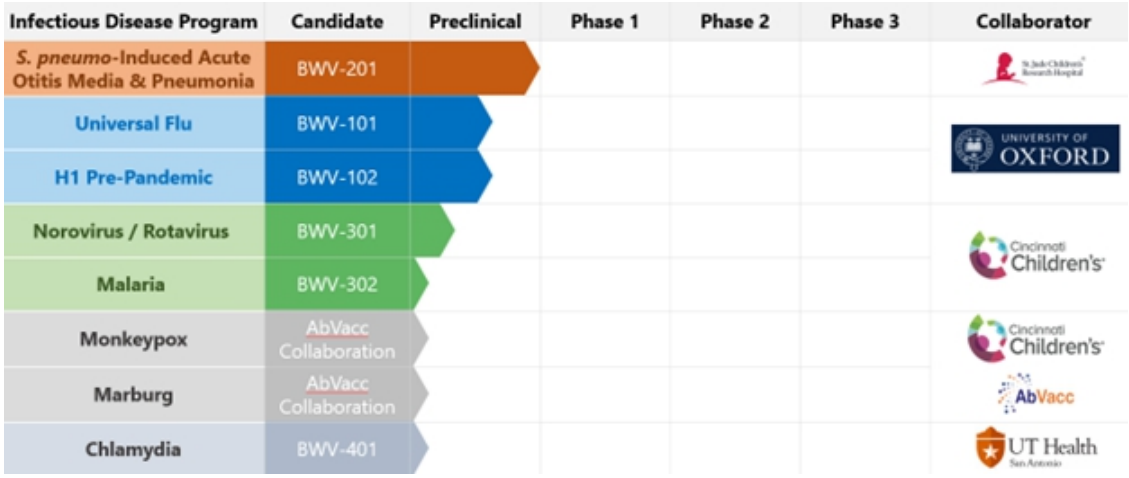
- ***Announced Timothy Ramdeen to the Board of Directors:*** In January 2023, the Company announced the appointment of seasoned public market and private equity investment leader, Timothy Ramdeen, to the Board. Mr. Ramdeen has nearly a decade of experience in private equity and hedge fund investing, capital markets, and company formation.

- ***Presented at Key Scientific and Investor Conferences:*** Throughout the first quarter of 2023 and to date, the Company's management presented its corporate overview and Company updates at key investor, financial, and scientific conferences to highlight the value story of the BWV pipeline and target leaders within the investment community. In January 2023, the Company presented an overview of its vaccine candidate pipeline and progress at Biotech Showcase 2023 during the 41st annual J.P. Morgan Healthcare Conference Week in San Francisco, California. In addition, the Company's management participated in the World Vaccine Congress Washington D.C. in April 2023. To promote ENTADFI® and connect with leaders in the urology space, the Company's management sponsored a booth at the American Urological Association Annual Meeting 2023 in Chicago, Illinois.

- ***Announced Joint Development Agreement with AbVacc for Marburg and Monkeypox Vaccine Candidates:*** In February 2023, the Company announced a partnership with AbVacc for the joint development of novel vaccine candidates targeting monkeypox, Marburg virus disease, among others. Vaccine candidates will utilize the Company's norovirus shell and protrusion virus-like particle platform, which allows for the presentation of multiple antigens on the surface of either the S or P particle of a norovirus backbone. Under this agreement, the Company and AbVacc will work collaboratively to identify appropriate antigens to use within this platform and will work toward clinical development of vaccine candidates.

- ***Signed Sponsored Research Agreement with The University of Texas Health Science Center at San Antonio for Non-Human Primate Study for Chlamydia Vaccine Development:*** In March 2023, the Company signed a sponsored research agreement with UT Health to initiate a non-human primate study for the Company's live attenuated, orally delivered Chlamydia vaccine, BWV-401. In this study, non-human primates will be vaccinated with BWV-401 and subsequently challenged against Chlamydia to validate they hypothesis that this vaccine is both safe and efficacious in a human-like model.

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



Since our inception in October 2018 until April 2023, when we acquired ENTADFI®, 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, aside from ENTADFI®, 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 the IPO, and the close of the Private Placements. We will continue to require additional capital to commercialize ENTADFI® and develop our vaccine candidates and fund operations for the foreseeable future. Accordingly, until such time as we can generate significant revenue from sales of our vaccine candidates or other products, 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, our expenditures on other research and development activities and commercialization activities. As of March 31, 2023, the Company had working capital of approximately $19.7 million and an accumulated deficit of approximately $22.2 million. We will need to raise additional capital to sustain operations within the one-year period following the issuance of the accompanying condensed financial statements.

While we believe that we can raise additional capital to fund our planned operations, until we generate revenue sufficient to support self-sustaining cash flows, if ever, we will need to raise additional capital to fund our continued operations, 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. These circumstances raise substantial doubt about our ability to continue as a going concern. The accompanying financial statements do not include any adjustment that might be necessary if the Company is unable to continue as a going concern.

We do not expect to generate any revenue from our vaccine candidates until we successfully complete development and obtain regulatory approval, which we expect will take a number of years. Our lead vaccine candidate, BWV-201, is anticipated to enter a Phase I clinical trial in 2024. Given ENTADFI® is currently approved, we expect to generate revenue from this product's sales in the near term. Although we anticipate sales of ENTADFI® to offset some expenses relating to its commercial scale up and development, as well as the development of our vaccine candidates in the future, 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.
- Commercialize and launch ENTADFI®

We rely and will continue to rely on third parties in the conduct of our preclinical studies and clinical trials as well as for the manufacturing and supply of our vaccine candidates and ENTADFI®. 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, clinical trial materials, and our commercial product. As we have a product in commercial stage, we are seeking to build a robust and efficient commercial team to accommodate this development. This includes appropriate personnel and third party relationships and contracts to execute our commercialization strategy. Accordingly, we also expect to incur significant commercialization expenses related to product sales, marketing, manufacturing and distribution for those products.

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 and ENTADFI®, 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 Notes 5 and 7 to each of our audited financial statements included in the Form 10-K and unaudited financial statements included elsewhere in this Report.

Ology MSA

In July 2019, we entered into a development and manufacturing master services agreement with Ology, pursuant to which Ology is obligated to perform manufacturing process development and clinical manufacture and supply of components.

The Company entered into an initial Project Addendum 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, at which point, the Company had paid Ology $100,000 for services. The second Project Addendum was executed May 21, 2021, pursuant to which 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%.

During 2022, the Company entered into three amendments to the Ology MSA, to adjust the scope of work defined in the second Project Addendum. The amendments resulted in a net increase to the Company's obligations under the second Project Addendum of $154,000. On March 27, 2023, the second Project Addendum to the Ology MSA was further amended to increase the scope of the project, resulting in an increase to the Company's obligations of $180,000 under the Ology MSA.

For additional details regarding our relationship with Ology, see Note 5 to our condensed 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 CHMC, pursuant to which we obtained the right to develop and commercialize certain CHMC patents and related technology directed at a virus-like particle vaccine platform that utilizes nanoparticle delivery technology, which may have potential broad application to develop vaccines for multiple infectious diseases.

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

U.S. Patent Application No.	U.S. Patent No.	Granted Claim Type	U.S. Expiration	Foreign Counterparts
12/797,396	8,486,421	Compositions of the vaccine/vaccine platform	1/13/2031	CN107043408B EP2440582B1 JP5894528B2
13/924,906	9,096,644	Method of treatment	9/20/2030	CN107043408B EP2440582B1 JP5894528B2
13/803,057	9,562,077	Compositions of the vaccine platform	4/10/2034	none
16/489,095	pending	pending**	[3/15/2038]*	Pending applications in Canada, China, EU, Hong Kong 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, 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, 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 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. On March 22, 2023, the Company entered into another amendment to the St. Jude Agreement, whereby the development milestone timeline was further revised. For additional details regarding our relationship with St. Jude, see Notes 5 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.

AbVacc Co-Development Agreement

On February 1, 2023, the Company entered into the Co-Development Agreement with AbVacc for the purpose of conducting research aimed at co-development of specific vaccine candidates, including monkeypox and Marburg virus disease with the potential to expand to others using the Norovirus nanoparticle platform, and to govern the sharing of materials and information, as defined in the agreement, for the Co-Development Project. Under the Co-Development Agreement, AbVacc and the Company will collaborate, through a joint development committee, to establish and implement a development plan or statement of work for each Co-Development Project targeted product. Under the Co-Development Agreement, either the Company or AbVacc, whichever party is the primary sponsor of any resulting product (as defined in the Co-Development Agreement), will be obligated to compensate the other party for certain milestone payments that would range between $2.1 million and $4.75 million, plus royalties of between 2% to 4%. The term of the Co-Development Agreement is three years from the effective date, unless previously terminated by either party, in accordance with the Co-Development Agreement.

Butantan Letter of Intent

On May 19, 2022, the Company and Instituto Butantan ("Butantan") entered into a letter of intent, pursuant to which the Company and Butantan intend to establish a future technological collaboration in order to improve Butantan's platform and develop the universal influenza vaccine candidate in collaboration with the Company.

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, 2023 and 2022

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

	Three Months Ended March 31, 2023	Three Months Ended March 31, 2022	$ Change	% Change
Operating expenses				
General and administrative	$ 1,766,022	$ 1,615,569	150,453	9.3%
Research and development	1,082,237	455,092	627,145	137.8%
Total operating expenses	2,848,259	2,070,661	777,598	37.6%
Loss from operations	(2,848,259)	(2,070,661)	(777,598)	37.6%
Total other income	(1,615)	—	(1,615)	*
Net loss	$ (2,846,664)	$ (2,070,661)	(775,983)	37.5%

* Not meaningful

General and Administrative Expenses

For the three months ended March 31, 2023, general and administrative expenses increased by $0.2 million compared to the same period in 2022. The increase was mainly due to an increase in professional fees of approximately $0.2 million and an increase in various business activities related to company growth and development such as business advisory services, travel, and rent expense totaling approximately $0.4 million. These increases were offset by a decrease in employee compensation of approximately $0.1 million as well as $0.3 million of a non-recurring expense in the three months ended March 31, 2022 to early terminate an agreement with an underwriter, with no similar expense in the current period.

Research and Development Expenses

For the three months ended March 31, 2023, research and development expenses increased by approximately $0.6 million compared to the same period in 2022. The increase was primarily attributable to an increase in preclinical development activities of approximately $0.3 million mainly related to BWV-101 and BWV-201, and an increase in research and development personnel costs of approximately $0.3 million.

Other Income

Other income relates to the change in fair value of the contingent warrant liability, which was incurred at the close of the April and August private placements during 2022. There was no other income or expense during the three months ended March 31, 2022.

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, aside from ENTADFI®, 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 $2.8 million for the three months ended March 31, 2023. As of March 31, 2023, we had an accumulated deficit of $22.2 million. We also generated negative operating cash flows of $4.4 million for the three months ended March 31, 2023. During April 2023, the Company completed an acquisition of assets relating to ENTADFI® that requires the Company to pay initial consideration of $20.0 million, of which $6.0 million was paid upon close, and $9.0 million of the remainder is due to the seller of the assets within one year of the date the accompanying condensed financial statements were issued. The remaining $5.0 million is due in September 2024.

As further discussed in Note 2 of the condensed financial statements included elsewhere in this Report, management has concluded that there is substantial doubt regarding our ability to continue as a going concern for one year from the issuance of the accompanying condensed financial statements.

We will require significant amounts of additional capital to continue to fund our continuing operations, satisfy existing and future obligations and liabilities, and otherwise support our working capital needs and business activities, including the commercialization of ENTADFI® and the development and commercialization of our current product candidates and future product candidates. Management's plans include generating product revenue from sales of ENTADFI®, which is subject to successful commercialization activities, some of which are outside of the Company's control, including but not limited to, securing contracts with wholesalers and third party payers, securing contracts with third-party logistics providers, obtaining required licensure is various jurisdictions, and building a salesforce, as well as attempting to secure additional required funding through equity or debt financings if available. However, 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 to date have been 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, commercialize ENTADFI®, expand our corporate infrastructure, including the costs associated with being a public company. 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 and in order to execute our long term business plan.

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, sales of ENTADFI®, 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 ENTADFI® or 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 ENTADFI® or 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, 2023	Three Months Ended March 31, 2022
Net cash used in operating activities	(4,446,083)	(886,091)
Net cash used in investing activities	(1,819)	(5,197)
Net cash provided by (used in) financing activities	(48,954)	17,572,063
Net increase (decrease) in cash	(4,496,856)	16,680,775

Cash Flows from Operating Activities

Net cash used in operating activities for the three months ended March 31, 2023 was $4.4 million, which primarily resulted from a net loss of $2.8 million, which was partially offset by noncash stock-based compensation of approximately $0.2 million, and a net change in our operating assets and liabilities of $1.8 million.

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.

Cash Flows from Investing Activities

Net cash used in investing activities for the three months ended March 31, 2023 and 2022 was $2,000 and $5,000, respectively, which resulted from purchases of property and equipment.

Cash Flows from Financing Activities

Net cash used in financing activities for the three months ended March 31, 2023 was $49,000, and resulted from $33,000 in purchases of treasury shares and $16,000 of payment in deferred offering costs.

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.

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. 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. 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. As of March 31, 2023, there have been no material changes to our critical accounting policies and estimates from those disclosed in “Management’s Discussion and Analysis of Financial Condition and Results of Operations – Critical Accounting Policies and Estimates,” included in our Annual Report on Form 10-K for the year ended December 31, 2022 filed with the SEC on March 9, 2023.

Quantitative and Qualitative Disclosures About Market Risk

We are a smaller reporting company as defined by Rule 12b-2 of the Securities Exchange Act of 1934, as amended (the “Exchange Act”), and are not required to provide the information otherwise required under this item.

JOBS Act

Section 107 of the Jumpstart Our Business Startups Act ("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.

Purchase of ENTADFI®

On April 19, 2023, the Company entered into the APA. Pursuant to, and subject to the terms and conditions of, the APA, the Company purchased substantially all of the assets related to the Seller's ENTADFI® business and assumed certain liabilities of the Seller . The Transaction closed on April 19, 2023.

The Company purchased substantially all of the Seller's assets, rights and property related to ENTADFI® for a total possible consideration of $100.0 million (as described below). The acquisition of ENTADFI® capitalizes on the demonstrable success of the FDA-approved drug ENTADFI® for treating benign prostatic hyperplasia and counteracting negative sexual side effects seen in men on alternative BPH therapies.

Furthermore, in connection with the Transaction, the Company assumed royalty and milestone obligations under an asset purchase agreement for tadalafil-finasteride combination entered into by the Seller and Camargo Pharmaceutical Services, LLC on December 11, 2017. The Camargo Obligations assumed by the Company include a 6% royalty on all sales of tadalafil-finasteride and sales milestone payments of up to $22.5 million.

Pursuant to the terms of the APA, the Company agreed to provide the Seller with initial consideration totaling $20.0 million, consisting of (i) $6.0 million paid upon the closing of the Transaction, (ii) an additional $4.0 million in the form of a non-interest bearing note payable due on September 30, 2023, and (iii) an additional $10.0 million in the form of two equal (i.e. each for $5.0 million) non-interest bearing notes payable, each due on April 19, 2024 and September 30, 2024.

Additionally, the terms of the APA require the Company to pay the Seller up to an additional $80.0 million based on the Company's net sales from the ENTADFI® business after closing. The Milestone Payments are payable as follows: (i) $10.0 million is payable if the Company's annual net sales from the ENTADFI® business equal or exceed $100.0 million, (ii) $20.0 million is payable if the Company's annual net sales from the ENTADFI® business equal or exceed $200.0 million, and (3) $50.0 million is payable if annual net sales from the ENTADFI® business equal or exceed $500.0 million. No more than one Milestone Payment shall be made for the achievement of each net sales milestone. There can be no assurance that the net sales milestones for payment of any of the Milestone Payments will be reached.

Corporate Name Change

On April 21, 2023, the Company filed an amendment to its A&R COI with the Secretary of State of Delaware to change its corporate name from "Blue Water Vaccines Inc." to "Blue Water Biotech, Inc." The name change was effective as of April 21, 2023.

In connection with the name change, the Company amended the Company's bylaws to reflect the corporate name Blue Water Biotech, Inc., also effective on April 21, 2023. No other changes were made to the bylaws.

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. Our management, with the participation of our Chief Executive Officer and Chief Financial Officer has evaluated the effectiveness of our disclosure controls and procedures. Management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving their objectives and management necessarily applies its judgment in evaluating the cost benefit relationship of possible controls and procedures. Based on that evaluation, our Chief Executive Officer and Chief Financial Officer have concluded that the Company's disclosure controls and procedures were not effective as of March 31, 2023, as a result of the material weaknesses described below.

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 in internal control over financial reporting existing as of March 31, 2023 are as follows:

- We failed to employ a sufficient number of staff to maintain optimal segregation of duties and to provide optimal levels of oversight in order to process financial information in a timely manner, analyze and account for complex, non-routine transactions, and prepare financial statements.

- We do not yet have adequate internal controls in place for the timely identification, approval or reporting of related party transactions.

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

Remediation of Material Weaknesses

We are committed to maintaining a strong internal control environment and implementing measures designed to help ensure that the material weaknesses are remediated as soon as possible. We believe we have made progress towards remediation and continue to implement our remediation plan for the material weaknesses, which includes steps to increase dedicated qualified personnel including financial consultants, improve reporting processes, and design and implement new controls. We have also implemented a related party transactions approval policy which our Board approved on June 24, 2022. Further, we have designed certain controls surrounding the identification, approval and reporting of related party transactions, which we expect to implement during 2023. 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, 2023, 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

There is substantial doubt about our ability to continue as a "going concern."

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, 2023, the Company had cash of approximately $20.3 million, working capital of approximately $19.7 million and an accumulated deficit of approximately $22.2 million. During April 2023, the Company completed an acquisition of assets that requires the Company to pay initial consideration of $20.0 million, of which $6.0 million was paid upon close, and $9.0 million of the remainder is due to the seller of the assets within one year of the date these accompanying condensed financial statements were issued. The remaining $5.0 million is due in September 2024.

The Company will require significant additional capital to fund its continuing operations, satisfy existing and future obligations and liabilities, and otherwise support the Company's working capital needs and business activities, including the commercialization of ENTADFI® and the development and commercialization of its current product candidates and future product candidates. Management's plans include generating product revenue from sales of ENTADFI®, which is subject to successful commercialization activities, some of which are outside of the Company's control, including but not limited to, securing contracts with wholesalers and third party payers, securing contracts with third-party logistics providers, obtaining required licensure in various jurisdictions, and building a salesforce, as well as attempting to secure additional required funding through equity or debt financings if available. 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, development and/or commercialization of products and product candidates, and it may take additional measures to reduce expenses in order to conserve its cash in amounts sufficient to sustain operations and meet its obligations. These conditions raise substantial doubt about the Company's ability to continue as a going concern for a period of time within one year after the date of the issuance of the condensed financial statements included elsewhere in this Report.

We expect to rely on third party manufacturers for ENTADFI®.

For the foreseeable future, we expect to and do rely on third-party manufacturers and other third parties to produce, package and store sufficient quantities of ENTADFI® to meet demand. ENTADFI® is complicated and expensive to manufacture. If our third-party manufacturers fail to deliver ENTADFI® for clinical use on a timely basis, with sufficient quality, and at commercially reasonable prices, we may be required to delay or suspend clinical trials or otherwise discontinue development and production of ENTADFI®. While we may be able to identify replacement third-party manufacturers or develop our own manufacturing capabilities for ENTADFI®, this process would likely cause a delay in the availability of ENTADFI® and an increase in costs. In addition, third-party manufacturers may have a limited number of facilities in which ENTADFI® can be produced, and any interruption of the operation of those facilities due to events such as equipment malfunction or failure or damage to the facility by natural disasters could result in the cancellation of shipments, loss of product in the manufacturing process or a shortfall in ENTADFI®.

In addition, regulatory requirements could pose barriers to the manufacture of ENTADFI®. Third-party manufacturers are required to comply with the FDA's cGMPs. As a result, the facilities used by any manufacturers of ENTADFI® must maintain a compliance status acceptable to the FDA. Holders of NDAs, or other forms of FDA approvals or clearances, or those distributing a regulated product under their own name, are responsible for manufacturing even though that manufacturing is conducted by a third-party contract manufacturing organization ("CMO"). Our third-party manufacturers will be required to produce ENTADFI® under FDA cGMPs in order to meet acceptable standards. Our third-party manufacturers may not perform their obligations under their agreements with us or may discontinue their business before the time required by us to commercialize our drug candidates. In addition, our manufacturers will be subject to ongoing periodic unannounced inspections by the FDA and corresponding state and foreign agencies for compliance with cGMPs and similar regulatory requirements. Failure by any of our manufacturers to comply with applicable cGMPs could result in sanctions being imposed on us, including fines, injunctions, civil penalties, delays, suspensions or withdrawals of approvals, operating restrictions, interruptions in supply, recalls, withdrawals, issuance of safety alerts and criminal prosecutions, any of which could have a material adverse effect on our business, financial condition, results of operations and prospects. Finally, we also could experience manufacturing delays if our CMOs give greater priority to the supply of other products over ENTADFI® or otherwise do not satisfactorily perform according to the terms of their agreements with us.

If any supplier for ENTADFI® experiences any significant difficulties in its manufacturing processes, does not comply with the terms of the agreement between us or does not devote sufficient time, energy and care to providing our manufacturing needs, we could experience significant interruptions in the supply of ENTADFI®, which could impair our ability to supply ENTADFI® at the levels required for our clinical trials or commercialization and prevent or delay its successful development and commercialization.

Disruptions to or significantly increased costs associated with transportation and other distribution channels for ENTADFI® may adversely affect our margins and profitability.

We expect to rely on the uninterrupted and efficient operation of third-party logistics companies to transport and deliver ENTADFI®. These third-party logistics companies may experience disruptions to the transportation channels used to distribute our products, including disruptions caused by the COVID-19 pandemic, increased airport and shipping port congestion, a lack of transportation capacity, increased fuel expenses, and a shortage of manpower or capital or due to other business interruptions. Disruptions to the transportation channels experienced by our third-party logistics companies may result in increased costs, including the additional use of airfreight to meet demand. Disruptions to this business model or our relationship with the third party if, for example, performance fails to meet our expectations, could harm our business.

We may fail or elect not to commercialize ENTADFI®.

We may not successfully commercialize ENTADFI®. We or our collaboration partners in any potential commercial marketing efforts of ENTADFI may not be successful in achieving widespread patient or physician awareness or acceptance of this product. Also, we may be subject to pricing pressures from competitive products or from governmental or commercial payors or regulatory bodies that could make it difficult or impossible for us to commercialize ENTADFI® successfully. Any failure to commercialize ENTADFI® could have a material adverse effect on our future revenue and our business.

If we fail to commercialize ENTADFI®, our business, financial condition, results of operations and prospects may be materially adversely affected and our reputation in the industry and in the investment community would likely be damaged.

We may not be able to gain and retain market acceptance for ENTADFI®.

Physicians may not prescribe ENTADFI®, which would prevent ENTADFI® from generating revenue. Market acceptance of ENTADFI® by physicians, patients and payors, will depend on a number of factors, many of which are beyond our control, including the following:

- the clinical indications for which ENTADFI® is approved, if at all;
- acceptance by physicians and payors of ENTADFI® as safe and effective treatment;
- the cost of treatment in relation to alternative treatments;

- the relative convenience and ease of administration of ENTADFI® in the treatment of the conditions for which it is intended;
- the availability and efficacy of competitive drugs;
- the effectiveness of our sales and marketing efforts;
- the extent to which ENTADFI® is approved for inclusion on formularies of hospitals and managed care organizations;
- the availability of coverage and adequate reimbursement by third parties, such as insurance companies and other health care payors, or by government health care programs, including Medicare and Medicaid;
- limitations or warnings contained in a product's FDA or other applicable regulatory agency's approved labeling; and
- prevalence and severity of adverse side effects.

Even if the medical community accepts that ENTADFI® is safe and efficacious for its approved indications, physicians may not immediately be receptive to the use or may be slow to adopt such products as an accepted treatment for the conditions for which it is intended. Without head-to-head comparative data, we will also not be able to promote ENTADFI® as being superior to competing products. If ENTADFI® does not achieve an adequate level of acceptance by physicians and payors, we may not generate sufficient or any revenue from this product. In addition, our efforts to educate the medical community and third-party payors on the benefits of our product may require significant resources and may never be successful.

In addition, even if ENTADFI® achieve market acceptance, we may not be able to maintain that market acceptance over time if:

- new products or technologies are introduced that are more favorably received than ENTADFI®, are more cost effective or render ENTADFI® obsolete;
- unforeseen complications arise with respect to use of ENTADFI®; or
- sufficient third-party insurance coverage or reimbursement does not remain available.

We may experience competition for ENTADFI®.

We are engaged in the marketing of a product in industries, including the pharmaceutical industry, that are highly competitive. The pharmaceutical industry is also characterized by extensive research and rapid technological progress. Potential competitors with respect to ENTADFI® in North America, Europe and elsewhere include major pharmaceutical companies, specialty pharmaceutical companies and biotechnology firms, universities and other research institutions and government agencies. Many of our competitors have substantially greater research and development and regulatory capabilities and experience, and substantially greater management, manufacturing, distribution, marketing and financial resources, than we have. We may be unable to compete successfully against current and future competitors, and competitive pressures could have a negative effect on our net revenues and profit margins.

Other parties have developed and marketed drugs for BPH that have been accepted by the physician, patient and payor communities. Many of these other products have also reached the point where they are now generic drugs, which means that they are sold at a very low price, a price which ENTADFI® may not be able to meet which could limit ENTADFI®'s reach into the physician, patient and payor communities, including government payors.

We may not be able to successfully implement our strategy to grow sales of ENTADFI in the U.S. market or, if authorized, in any foreign market.

We may not be able to expand sales of ENTADFI® through partnering with telemedicine or other partners or through our own commercialization efforts. We may not be able to command a price with private and government payors for ENTADFI® that would justify our devotion of significant resources to attempting to grow sales of ENTADFI®. We may not be able to compete efficiently or effectively in a mature BPH market which is heavily generic. Failure to grow sales of ENTADFI® would have a negative effect on our revenue and future plans.

For additional risks relating to our operations, see the section titled "Risk Factors" contained in our Annual Report on Form 10-K, filed with the SEC on March 9, 2023. 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.

Issuer Purchases of Equity Securities

On November 10, 2022, the Board approved a share repurchase program to allow for the Company to repurchase up to 5.0 million shares of common stock, with discretion to management to make purchases subject to market conditions. The maximum purchase price is $2.00 per share and there is no expiration date for this program.

Below is a summary of stock repurchases for the three months ended March 31, 2023. *See Note 6 to our condensed financial statements included elsewhere in this Report for more information regarding our stock repurchase program.*

Period	Total Number of Shares Repurchased	Average Price Paid Per Share	Total Number of Shares Purchased as Part of Publicly Announced Plan	Maximum Number of Shares that May Yet be Purchased Under the Plan (1)
Beginning repurchase authority	459,729			4,690,559
March 1 – March 31, 2023				
Shares repurchased	32,638	$ 1.03	32,638	4,507,633
Total	492,367		492,367	4,507,633

(1) On November 10, 2022, the Board approved a share repurchase program to allow for the Company to repurchase up to 5.0 million shares of the Company's common stock at a price of $1.00 per share, with discretion to management to make purchases subject to market conditions. On November 18, 2022 the Board approved an increase in the price to $2.00 per share.

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 Report.

EXHIBIT INDEX

Exhibit Number	Description of Document
3.1	Certificate of Amendment to the Company's Second Amended and Restated Certificate of Incorporation.(1)
3.2	Second Amended and Restated Bylaws of the Company.(1)
10.1	Patent & Technology License Agreement, dated November 18, 2022, between the Company and the University of Texas Health Science Center at San Antonio.*
10.2	Co-Development Agreement, dated February 1, 2023, between the Company and AbVacc, Inc.*
10.3	At-the-Market Offering Agreement, dated March 29, 2023, between the Company and H.C. Wainwright & Co., LLC.(2)
10.4	Asset Purchase Agreement, dated April 19, 2023, between the Company and Veru Inc.(3)†
10.5	Form of Non-Competition and Non-Solicitation Agreement, dated April 19, 2023.(3)
10.6	Promissory Note, dated April 19, 2023.(4)
10.7	Promissory Note, dated April 19, 2023.(4)
10.8	Promissory Note, dated April 19, 2023.(4)
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.*
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.*
32.1	Certification of the Principal Executive Officer pursuant to 18 U.S.C. 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.**
32.2	Certification of the Principal Financial Officer pursuant to 18 U.S.C. 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.**
101.INS*	Inline XBRL Instance Document.
101.SCH*	Inline XBRL Taxonomy Extension Schema Document.
101.CAL*	Inline XBRL Taxonomy Extension Calculation Linkbase Document.
101.DEF*	Inline XBRL Taxonomy Extension Definition Linkbase Document.
101.LAB*	Inline XBRL Taxonomy Extension Label Linkbase Document.
101.PRE*	Inline XBRL Taxonomy Extension Presentation Linkbase Document.
104	Cover Page Interactive Data File (formatted as Inline XBRL and contained in Exhibit 101).

* Filed herewith.
** Furnished herewith.

† Certain of the exhibits and schedules to this Exhibit have been omitted in accordance with Regulation S-K Item 601(a)(5). The Registrant agrees to furnish a copy of all omitted exhibits and schedules to the SEC upon its request.

(1) Incorporated by reference to the Registrant's Current Report on Form 8-K filed with the SEC on April 24, 2023.
(2) Incorporated by reference to the Registrant's Current Report on Form 8-K filed with the SEC on March 29, 2023.
(3) Incorporated by reference to the Registrant's Current Report on Form 8-K filed with the SEC on April 20, 2023.
(4) Incorporated by reference to the Registrant's Post-Effective Amendment No. 1 to Form S-1 on Form S-3 filed with the SEC on April 28, 2023.

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 Biotech, Inc.

Date: May 12, 2023

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

Date: May 12, 2023

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

PATENT & TECHNOLOGY LICENSE AGREEMENT
AGT. NO. HSC-1316-LA1

This Patent and Technology License Agreement is between the Licensor and the Licensee identified below (collectively, "Parties", or singly, "Party").

No binding agreement between the Parties will exist until this Patent & Technology License Agreement has been signed by both Parties. Unsigned drafts of this Patent & Technology License Agreement shall not be considered offers.

Background

Licensor owns or controls Licensed Subject Matter (defined in Exhibit A). Licensee desires to secure the right and license to use, develop, manufacture, market, and commercialize the Licensed Subject Matter. Licensor has determined that such use, development, and commercialization of the Licensed Subject Matter is in the public's best interest and is consistent with Licensor's educational and research missions and goals. Licensor desires to have the Licensed Subject Matter developed and used for the benefit of Licensee, the inventors, Licensor, and the public.

NOW, THEREFORE, in consideration of the mutual covenants and premises herein contained, the Parties hereby agree as follows:

The Terms and Conditions of Patent & Technology License Agreement attached hereto as Exhibit A are incorporated herein by reference in their entirety (the "Terms and Conditions"). In the event of a conflict between provisions of this Patent & Technology License Agreement and the Terms and Conditions, the provisions in this Patent & Technology License Agreement shall govern. Unless defined in this Patent & Technology License Agreement, capitalized terms used in this Patent & Technology License Agreement shall have the meanings given to them in the Terms and Conditions.

The section numbers used in the left hand column in the table below correspond to the section numbers in the Terms and Conditions.

1. Definitions					
	Effective Date	Date of Last Signature			
	Licensor	The University of Texas Health Science Center at San Antonio, on behalf of the Board of Regents ("Board") of The University of Texas System, an agency of the State of Texas, whose address is 210 West 7th Street, Austin, Texas, 78701			
	Licensee	Blue Water Vaccines Inc, a Delaware Corporation with its principal place of business at 201 E. Fifth Street, Cincinnati, OH 45202			
	Contract Year and Contract Quarters	Contract Year is 12-month period ending on December 31 and Contract Quarters are 3-month periods ending on March 31, June 30, Sept. 30, Dec. 31			
	Territory	Worldwide			
	Licensed Field	Vaccines			
	Excluded Field	Vectors			
	Patent Rights				
	App. No./ Date of Filing	**Title**	**Inventor(s)**	**Jointly Owned?**	**Prosecution Counsel**
	U.S. Provisional Application No. 62/118,961 filed 02/20/2015 OTC Ref.: HSC-1316	"Methods and compositions for attenuated chlamydia as vaccine and vector"	Guangming Zhong	No	Myers, Bigel, Sibley & Sajovec
	U.S. Provisional Application No. 63/424,281 filed 11/10/2022 OTC Ref.: HSC-1761	"Compositions and Methods for Treating and Preventing Human Chlamydial Infections and Diseases Using Attenuated Animal Chlamydia"	Guangming Zhong	No	Ballard Spahr
	USPTO Entity Status as of Effective Date	Small			

2.4. Diligence Milestones			
	Milestones and deadlines	**Business Milestones**	**Deadlines**
		1. Raise sufficient investment capital to achieve Milestone Event 3.1(b)(1)	October 1, 2022
		2. Raise sufficient investment capital to achieve Milestone Event 3.1(b)(4)	September 30, 2023
		3. Raise sufficient investment capital to achieve Milestone Event 3.1(b)(5)	December 31, 2027
		Scientific Milestones	
		1. Complete initial non-human primate studies	June 30, 2023
		2. Complete IND-enabling pre-clinical work	May 31, 2026
		3. IND filed in the United States	June 30, 2026
		4. Phase I Clinical Trial – First Patient Enrolled anywhere in the Territory	September 1, 2026
		5. Phase II Clinical Trial – First Patient Enrolled anywhere in the Territory	March 31, 2028
		6. Phase III Clinical Trial – First Patient Enrolled anywhere in the Territory	March 31, 2030
		7. Regulatory Approval of Licensed Product in the United States	December 31, 2035
		8. Regulatory Approval of Licensed Product in Europe, Japan, or China	No later than six months after fulfillment of Scientific Milestone Event No. 7, the Parties will negotiate, in good faith, a reasonable deadline for completion of this milestone.
3. Compensation			
3.1(a)	**Patent expenses due upon Effective Date**	**Amount**	**based on invoices received as of:**
		$ 82,817.31	09/30/2022
3.1(b)	**Milestone fees**	**Milestone Events**	**Milestone Fees**
		1. Complete initial non-human primate studies	$50,000.00
		2. Complete IND-enabling pre-clinical work	$0.00
		3. IND filed in the United States	$0.00
		4. Phase I Clinical Trial – First Patient Enrolled anywhere in the Territory	$100,000.00
		5. Phase II Clinical Trial – First Patient Enrolled anywhere in the Territory	$200,000.00
		6. Phase III Clinical Trial – First Patient Enrolled anywhere in the Territory	$300,000.00
		7. Regulatory Approval of Licensed Product in the United States	$1,000,000.00
		8. Regulatory Approval of Licensed Product in Europe, Japan, or China	$500,000.00
3.1(c)	**Scheduled license fee payments**	$100,000.00 due thirty days after Effective Date $20,000.00 for Contract Year ending 2023 $20,000.00 for Contract Year ending 2024 $20,000.00 per Contract Year ending 2025 $20,000.00 for Contract Year ending 2026 $40,000.00 for Contract Year ending 2027 $40,000.00 for Contract Year ending 2028 $60,000.00 for Contract Year ending 2029 and each Contract Year thereafter	

3.1(d)	**Sublicense Fees**	20% of Non-Royalty Sublicensing Consideration	
3.1(e)	**Assignment fee**	$100,00.00	
3.2	**Running royalty rate (applies to Sales by Licensee, Affiliates and Sublicensees)**	(a) Licensed Products and Licensed Services covered by a Valid Claim	5%
		(b) Licensed Products and Licensed Services not covered by a Valid Claim	3%
3.3	**Minimum Royalties**	None	
3.6	**Equity Consideration**	None	

18. Contact Information

Licensee Contacts	**Licensor Contacts**
Contact for Notice: Attn: Erin Henderson 201 E Fifth St, Suite 1900, Cincinnati, OH 45202 Phone: 404-405-6315 E-mail: ehenderson@bluewatervaccines.com	Contact for Notice: Attn: Assistant Vice President Office of Technology Commercialization The University of Texas Health Science Center at San Antonio South Texas Research Facility (STRF) 8403 Floyd Curl Drive, MSC 7746 San Antonio, Texas 78229-3904 Phone: 210-562-4000 E-mail: licensing@uthscsa.edu
Accounting contact: Attn: Betty Rose 201 E Fifth St, Suite 1900, Cincinnati, OH 45202 Phone: 513620-4101 E-mail: ap@bluewatervaccines.com	Accounting contact: Same as Contact for Notice Checks payable to the "University of Texas Health Science Center at San Antonio, Office of Technology Commercialization." For payment by wire transfer, Licensee will pay all wire transfer fees. Send funds to the following bank account: Frost National Bank 100 West Houston Street San Antonio, Texas 78205 Swift code: FRSTUS44 ABA 114000093 Account Name: UTHSC Electronic Funds Transfers Account # - 019989967
Patent prosecution contact: Attn: Erin Henderson 201 E Fifth St, Suite 1900, Cincinnati, OH 45202 Phone: 404-405-6315 E-mail: ehenderson@bluewatervaccines.com	Patent prosecution contact: Attn: Patent Manager Office of Technology Commercialization 8403 Floyd Curl Drive, MSC 7746 San Antonio, Texas 78229-3900 Phone: 210-562-4000 E-mail: patents@uthscsa.edu

20. Special Provision. The Parties hereby agree to the following special provisions set forth in this Section 20 with respect to this Patent & Technology License Agreement.

None.

21. No Other Promises and Agreements; Representation by Counsel. Licensee expressly warrants and represents and does hereby state and represent that no promise or agreement which is not herein expressed has been made to Licensee in executing this Patent & Technology License Agreement except those explicitly set forth herein and in the Terms and Conditions, and that Licensee is not relying upon any statement or representation of Licensor or its representatives. Licensee is relying on Licensee's own judgment and has had the opportunity to be represented by legal counsel. Licensee hereby warrants and represents that Licensee understands and agrees to all terms and conditions set forth in this Patent & Technology License Agreement and said Terms and Conditions.

22. Deadline for Execution by Licensee. If this Patent & Technology License Agreement is executed first by the Licensor and is not executed by the Licensee and received by the Licensor at the address and in the manner set forth in Section 18 of the Terms and Conditions within 30 days of the date of signature set forth under the Licensor's signature below, then this Patent & Technology License Agreement shall be null and void and of no further effect.

IN WITNESS WHEREOF, the Parties hereto have caused their duly authorized representatives to execute this Patent & Technology License Agreement.

LICENSOR: The Board of Regents of The University of Texas System

By /s/ Ginny Gomez-Leon
Ginny Gomez-Leon, MBA, CPA
Vice President and Chief Financial Officer
University of Texas Health Science Center at San Antonio

Date 11/18/2022

LICENSEE: Blue Water Vaccines, Inc

By /s/ Joseph Hernandez
Joseph Hernandez
CEO & Chairman of the Board

Date 11/18/2022

Approved as to form:

By /s/ John Gebhard
John Gebhard, Ph.D.
Assistant Vice President
Office of Technology Commercialization

Date 11/18/2022

EXHIBIT A
TERMS AND CONDITIONS OF PATENT & TECHNOLOGY LICENSE

These Terms and Conditions of Patent & Technology License ("Terms and Conditions") are incorporated by reference into the Patent & Technology License Agreement to which they are attached. All Section references in these Terms and Conditions shall be references to provisions in these Terms and Conditions unless explicitly stated otherwise.

1. Definitions

"**Affiliate**" means any business entity more than 50% owned by Licensee, any business entity which owns more than 50% of Licensee, or any business entity that is more than 50% owned by a business entity that owns more than 50% of Licensee.

"Agreement" means collectively (i) these Terms and Conditions, and (ii) the Patent & Technology License Agreement.

"**Contract Quarter**" means the three-month periods indicated as the Contract Quarter in Section 1 of the Patent & Technology License Agreement, or any stub period thereof at the commencement of the Agreement or the expiration or termination of the Agreement.

"**Contract Year**" means the 12-month periods indicated as the Contract Year in Section 1 of the Patent & Technology License Agreement, or any stub period thereof at the commencement of the Agreement or the expiration or termination of the Agreement.

"**Effective Date**" means the date indicated as the Effective Date in Section 1 of the Patent & Technology License Agreement.

"Excluded Field" means the field indicated as the Excluded Field identified in Section 1 of the Patent & Technology License Agreement.

"**Fair Market Value**" means the cash consideration an unaffiliated, unrelated buyer would pay in an arm's length sale of a substantially identical item sold in the same quantity, under the same terms, and at the same time and place.

"FDA" means United States Food and Drug Administration.

"First Patient Enrolled" means the first date on which a clinical trial subject or a clinical trial subject's legally authorized representative provides informed consent to participate in the clinical trial.

"**Government**" means any agency, department or other unit of the United States of America or the State of Texas.

"Gross Consideration" means all cash and non-cash consideration (e.g., securities).

"Inventors" (or singly, **"Inventor"**) means the inventors identified in the definition of Patent Rights in Section 1 of the Patent & Technology License Agreement.

"IND" means an investigational new drug application and any amendments thereto relating to the use of Licensed Product in the United States or the equivalent application in any other jurisdiction in the Territory, the filing of which is necessary to legally commence clinical testing of pharmaceutical products in humans.

"Licensed Field" means the field indicated as the Licensed Field identified in Section 1 of the Patent & Technology License Agreement.

"**Licensed Process**" means a method or process whose practice or use is covered by a Valid Claim or uses Technology Rights.

"**Licensed Product**" means any product or component (i) whose Regulatory Approval, manufacture, use, Sale, offer for Sale or import is covered by any Valid Claim or incorporates any Technology Rights, or (ii) which is made using a Licensed Process or another Licensed Product.

"**Licensed Service**" means performance of a service for any consideration using a Licensed Product, or the practice of a Licensed Process. For clarity, research and development of Licensed Products by Licensee, its Affiliates, or a Sublicensee does not constitute a Licensed Service.

"Licensed Subject Matter" means Patent Rights and/or Technology Rights

"**Licensee**" means the Party identified as the Licensee in Section 1 of the Patent & Technology License Agreement.

"**Licensor**" means the Party identified as the Licensor in Section 1 of the Patent & Technology License Agreement.

"**Milestone Fees**" means all fees identified as Milestone Fees in Section 3.1(b) of the Patent & Technology License Agreement.

"**Net Product Sales**" means the Gross Consideration from the Sale of Licensed Products less the following items directly attributable to the Sale of such Licensed Products that are specifically identified on the invoice for such Sale and borne by the Licensee, Affiliates, or Sublicensees as the seller: (a) discounts and rebates actually granted; (b) sales, value added, use and other taxes and government charges actually paid, excluding income taxes; (c) import and export duties actually paid; (d) freight, transport, packing and transit insurance charges actually paid or allowed; and (e) other amounts actually refunded, allowed or credited due to rejections or returns, but not exceeding the original invoiced amount.

Net Product Sales exclude a reasonable quantity used internally solely for testing or quality control purposes, marketing or demonstration purposes, or seeking governmental approval (e.g., U.S. Food and Drug Administration clinical trial).

"Net Service Sales" means the Gross Consideration received from the Sale of Licensed Services less the following items, directly attributable to the Sale of such Licensed Services that are specifically identified on the invoice for such Sale and borne by the Licensee, Affiliates, or Sublicensees as the seller: (a) discounts and rebates actually granted; (b) sales, value added, use and other taxes and government charges actually paid, excluding income taxes; and (c) other amounts actually refunded, allowed or credited due to rejections or re-works, but not exceeding the original invoiced amount.

"Non-Royalty Sublicensing Consideration" means the Gross Consideration received by the Licensee or its Affiliate from a Sublicensee in consideration of the grant of a sublicense under the Licensed Subject Matter (including, without limitation, license or option or distribution fees, fees to maintain license rights, and bonus/milestone payments), but excluding amounts received as running royalties, a profit share, or other revenue sharing based on Net Product Sales or Net Service Sales for which Licensor receives a running royalty under Section 3.2. For the avoidance of doubt, Non-Royalty Sublicensing Consideration shall not include bona fide: (a) running royalties received by Licensee or an Affiliate based on Net Product Sales or Net Service Sales that are royalty-bearing to Licensor under Section 3.2, (b) purchase price for Licensee's stock or other securities not in excess of Fair Market Value, and (c) amounts paid and used exclusively for research and development of Licensed Products or Licensed Services by Licensee.

"**Patent & Technology License Agreement**" means the particular Patent & Technology License Agreement to which these Terms and Conditions are attached and incorporated into by reference.

"**Patent Rights**" means the Licensor's rights in: (a) the patents and patent applications listed in Section 1 of the Patent & Technology License Agreement; (b) all non-provisional patent applications that claim priority to any of the provisional applications listed in Section 1 of the Patent & Technology License Agreement to the extent the claims of such non-provisional applications are entitled to claim priority to such provisional applications; (c) all divisionals and continuations of the non-provisional patent applications identified in (a) and (b), above; (d) all reissues, reexaminations, extensions, and foreign counterparts of any of the patents or patent applications identified in (a), (b) or (c), above; and (e) any patents that issue with respect to any of the patent applications listed in (a), (b) , (c) or (d), above. From time to time during the term of the Agreement, upon written agreement by both Parties, Licensee and Licensor shall update the list of all patent applications and patents within the Patent Rights.

"Phase I Clinical Trial" means the initial introduction of Licensed Product into humans.

"Phase II Clinical Trial" means a clinical trial to evaluate the safety and effectiveness of Licensed Product for a particular indication in humans.

"Phase III Clinical Trial" means a clinical trial that is designed to gather additional information about the effectiveness and safety of Licensed Product and evaluate the overall benefit-risk relationship of the Licensed Product and to define warnings, precautions, and adverse reactions that are associated with the Licensed Product in the dosage range to be prescribed.

"Prosecution Counsel" means outside patent counsel that is mutually agreeable to both Parties, whereby such counsel enters into an appropriate contract and joint representation waiver with Board and the State of Texas Attorney General's Office, and copies University on all patent documentation and correspondence.

"**Quarterly Payment Deadline**" means the day that is 30 days after the last day of any particular Contract Quarter.

"**Regulatory Approval**" means the first letter acknowledging approval and/or clearance received from the FDA or other Regulatory Authority for a Licensed Product or Licensed Service in that national jurisdiction within the Territory (whether CE mark, PMA, NDA, BLA, ANDA, 510(k)), or a comparable regulatory approval or clearance letter received from a Regulatory Authority). For Japan, the definition of Regulatory Approval includes a conditional, time-limited marketing authorization.

"**Regulatory Authority**" means the governmental authority responsible for granting any necessary licenses or approvals for the marketing, Sale and use of a Licensed Product or Licensed Service in a particular national jurisdiction, including without limitation FDA, European Medicines Agency or Koseisho (i.e. the Japanese Ministry of Health and Welfare).

"**Sell, Sale or Sold**" means any transfer or other disposition of Licensed Products or Licensed Services for which consideration is received by Licensee, its Affiliates or Sublicensees. A Sale of Licensed Products or Licensed Services will be deemed completed at the time Licensee or its Affiliate or its Sublicensee invoices, ships, performs, or receives payment for Licensed Products or Licensed Services, whichever occurs first.

"**Sublicense Agreement**" means any agreement or arrangement pursuant to which Licensee (or an Affiliate or Sublicensee) grants to any third party any of the license rights granted to the Licensee under the Agreement.

"**Sublicense Fee**" means the fee specified in Section 3.1(d) of the Patent & Technology License Agreement.

"**Sublicensee**" means any entity to whom an express sublicense has been granted under the Patent Rights and/or Technology Rights. For clarity, a third party wholesaler or distributor who has no significant responsibility for marketing and promotion of the Licensed Product or Licensed Services within its distribution territory or field (i.e., the third party simply functions as a reseller), and who does not pay any consideration to Licensee or an Affiliate for such wholesale or distributor rights, shall not be deemed a Sublicensee; and the resale by such a wholesaler or distributor shall not be treated as royalty bearing Net Sales by a Sublicensee provided that a royalty is being paid by Licensee for the initial transfer to the wholesaler or distributor pursuant to Section 3.2. This definition does not limit Licensee's rights to grant or authorize sublicenses under the Agreement.

"**Technology Rights**" means Licensor's rights in technical information, know-how, processes, procedures, compositions, devices, methods, formulas, protocols, techniques, designs, drawings or data created before the Effective Date by Inventors while employed at the Licensor and within the Licensed Field which are not covered by a Valid Claim but which are necessary for practicing inventions claimed in patents and/or patent applications listed in the definition of Patent Rights whether outstanding, expired or abandoned.

"**Territory**" means the territory so indicated as the Territory in Section 1 of the Patent & Technology License Agreement.

"Vaccine" means a process or composition (as described in Patent Rights) that increases a subject's immune reaction to an immunogen (e.g., by providing an active immune response), and therefore its ability to resist, overcome and/or recover from infection (i.e., a protective immune response).

"Valid Claim" means a claim of (i) an issued and unexpired patent included within the Patent Rights unless the claim has been held unenforceable or invalid by the final, un-reversed, and un-appealable decision of a court or other government body of competent jurisdiction, has been irretrievably abandoned or disclaimed, or has otherwise been finally admitted or determined to be invalid, un-patentable or unenforceable, whether through reissue, reexamination, disclaimer or otherwise, or (ii) a pending patent application within the Patent Rights to the extent the claim continues to be prosecuted in good faith.

"Vector" means a cell or cells (of the technology described in Patent Rights) that function as a nucleic acid delivery vehicle.

2. License Grant and Commercialization

2.1 Grant

(a) Licensor grants to Licensee a royalty-bearing exclusive license under Patent Rights to manufacture, have manufactured, distribute, have distributed, use, offer for Sale, Sell, lease, loan and/or import Licensed Products in the Licensed Field in the Territory and to perform Licensed Services in the Licensed Field in the Territory.

(b) Licensor grants to Licensee a royalty-bearing non- exclusive license under Technology Rights to manufacture, have manufactured, distribute, have distributed, use, offer for Sale, Sell, lease, loan and/or import Licensed Products in the Licensed Field in the Territory and to perform Licensed Services in the Field in the Territory.

(c) This grant is subject to (i) the payment by Licensee to Licensor of all consideration required under the Agreement, (ii) any rights of, or obligations to, the Government as set forth in Section 11.2 (Government Rights), and (iii) rights retained by Licensor to:

(1) Publish the scientific findings from research related to the Patent Rights; and

(2) Use the Licensed Subject Matter for teaching, research, patient care, education, and other educationally-related purposes; and

(3) Grant rights to, and transfer material embodiments of, the Licensed Subject Matter to other academic institutions or non-profit research institutions for the purposes identified in clauses (1) and (2) above.

(d) Licensor reserves all rights not expressly granted in the Agreement and disclaims the grant of any implied rights to Licensee.

Nothing in this Agreement will be construed as conferring by implication, estoppel, or otherwise any license or rights under Patent Rights in the Excluded Field or under Technology Rights in the Excluded Field or to perform Licensed Services in the Excluded Field.

2.2 Affiliates

Licensee may extend the license granted herein to any Affiliate provided that the Affiliate agrees in writing to be bound by the Agreement to the same extent as Licensee. For the sake of clarity, any specific reference to "Licensee" herein shall include such Affiliate regardless of whether a specific reference to an "Affiliate" is made in such provision. Licensee agrees to deliver such written agreement to Licensor within 30 calendar days following execution.

2.3 Sublicensing

Licensee has the right to grant Sublicense Agreements under the Licensed Subject Matter consistent with the terms of the Agreement, subject to the following:

(a) A Sublicense Agreement shall not exceed the scope and rights granted to Licensee hereunder. Sublicensee must agree in writing to be bound by the applicable terms and conditions of the Agreement and shall indicate that Licensor is a third party beneficiary of the Sublicense Agreement. In the event of termination of this Agreement, continued sublicense rights shall be governed by Section 7.5(a) (Effect of Termination). Licensee may grant a Sublicensee the right to grant further sub-Sublicense Agreements, in which case such sub-Sublicense Agreements shall be treated as "Sublicense Agreements" and such sub-Sublicensees shall be treated as "Sublicensees" for purposes of the Agreement.

(b) Licensee shall deliver to Licensor a true, complete, and correct copy of each Sublicense Agreement granted by Licensee, Affiliate or Sublicensee, and any modification or termination thereof, within 30 days following the applicable execution, modification, or termination of such Sublicense Agreement. If the Sublicense Agreement is not in English, Licensee shall provide Licensor an accurate English translation in addition to a copy of the original agreement.

(c) Notwithstanding any such Sublicense Agreement, Licensee will remain primarily liable to Licensor for all of the Licensee's duties and obligations contained in the Agreement, including without limitation the payment of running royalties due under Section 3.2 whether or not paid to Licensee by a Sublicensee. Any act or omission of a Sublicensee that would be a breach of the Agreement if performed by Licensee will be deemed to be a breach by Licensee. Each Sublicense Agreement will contain a right of termination by Licensee in the event that the Sublicensee breaches the payment or reporting obligations affecting Licensor or any other terms and conditions of the Sublicense Agreement that would constitute a breach of the Agreement if such acts were performed by Licensee.

2.4 Diligent Commercialization

Licensee by itself or through its Affiliates and Sublicensees will use diligent efforts to make Licensed Products and/or Licensed Services (as applicable) commercially available in the Licensed Field within the Territory. Without limiting the foregoing, Licensee will

(a) maintain a bona fide, funded, ongoing and active research, development, manufacturing, regulatory, marketing or sales program (all as commercially reasonable) to make Licensed Products and/or Licensed Services commercially available to the public as soon as commercially practicable; and

(b) fulfill the milestone events specified in Section 2.4 of the Patent & Technology License Agreement by the deadlines indicated therein.

If the obligations under this Section 2.4 are not fulfilled, Licensor may treat such failure as a breach in accordance with Section 7.3(b).

2.5 Litigation by Sublicensee

In each Sublicense Agreement the following clauses must be included:

In the event Sublicensee brings an action seeking to invalidate or render unenforceable any Licensed Patent:

(a) Sublicensee shall double the payment paid to the Licensee during the pendency of such action. Moreover, should the outcome of such action determine that any claim of a patent challenged by the Sublicensee is both valid and infringed by a Licensed Product, Sublicensee shall pay triple the payment paid under the original Sublicense Agreement;

(b) Sublicensee shall have no right to recoup any royalties paid before or during the period of challenge;

(c) Sublicensee shall not pay royalties into any escrow or other similar account; and

(d) any dispute regarding the validity of any Licensed Patent shall be litigated in the courts located in Bexar County Texas, and the parties agree not to challenge personal jurisdiction in that forum.

Sublicensee shall provide written notice to Licensor at least three (3) months prior to bringing an action seeking to invalidate or render unenforceable a Licensed Patent. Sublicensee shall include with such written notice an identification of all prior art it believes invalidates any claim of the Licensed Patent.

3. Compensation

In consideration of rights granted to Licensee, Licensee will pay Licensor the following fees and royalties. All fees and royalties are not refundable and are not creditable against other fees and royalties. Each payment will reference the Patent & Technology License Agreement number and will be sent to Licensor's payment and accounting contact in Section 18 (Notices) of the Patent & Technology License Agreement.

3.1 Non-Royalty Payments due from Licensee

(a) *Patent Expenses*. Licensee will reimburse Licensor for the past patent expenses stated in Section 3.1(a) of the Patent & Technology License Agreement within 15 days after the Effective Date. The stated amount is the current estimate for past patent expenses based on invoices received by the Licensor through the stated date. Licensee's obligations to pay all past and future patent expenses pursuant to Section 6 (Patent Expenses and Prosecution) will not be limited by such amount.

(b) *Milestone Fees*. Licensee will pay Milestone Fees indicated in Section 3.1(b) of the Patent & Technology License Agreement by the Quarterly Payment Deadline for the Contract Quarter in which the milestone events set forth in Section 3.1(b) of the Patent & Technology License Agreement are achieved.

If the Regulatory Authority authorizes Licensee to combine or skip any of Milestone Events 4-6, the amount due under Section 3.1(b) for the event not completed shall be payable on the next Milestone Event deadline. In no event shall Licensee's obligation to pay the milestone fees under 3.1(b) be reduced due to a Regulatory Authority's authorization to combine or skip any of Milestone Events 4-6.

(c) *Scheduled License Fees*. Licensee will pay license fees in the amounts set forth in Sections 3.1(c) of the Patent & Technology License Agreement in accordance with the stated schedule.

(d) *Sublicense Fees*. Licensee will pay Sublicense Fees indicated in Section 3.1(d) of the Patent & Technology License Agreement, if applicable, on or before the Quarterly Payment Deadline for the Contract Quarter.

(e) *Assignment Fee*. Licensee will pay the assignment fee set forth in Section 3.1(e) of the Patent & Technology License Agreement within 15 days of the assignment of the Agreement by the Licensee.

3.2 Royalties

Licensee will pay running royalties on Net Product Sales and Net Service Sales in each Contract Quarter on or before the Quarterly Payment Deadline for such Contract Quarter, as follows: (a) at the rate set forth in Section 3.2(a) of the Patent & Technology License Agreement on Net Product Sales and Net Service Sales in each Contract Quarter for Licensed Products and Licensed Services covered by one or more Valid Claims; and (b) at the rate set forth in Section 3.2(b) of the Patent & Technology License Agreement on Net Product Sales and Net Service Sales in each Contract Quarter for Licensed Products and Licensed Services not covered by a Valid Claim. No royalty shall be payable under this Section 3.2 with respect to (i) Sales to an Affiliate or Sublicensee of a particular unit of Licensed Product that is used by such Affiliate or Sublicensee to perform a Licensed Service if Licensor is paid a royalty on the Sale of such Licensed Service, (ii) the Sale of Licensed Products between or among Licensee, its Affiliates, and Sublicensees for re-sale purposes, provided Licensor is paid a royalty with respect to the re-sale, or (iii) payments that constitute Non-Royalty Sublicensing Consideration.

3.3 Minimum Royalties

If royalties paid to Licensor do not reach the minimum royalty amounts stated in Section 3.3 of the Patent & Technology License Agreement for the specified periods, Licensee will pay Licensor on or before the Quarterly Payment Deadline for the last Contract Quarter in the stated period an additional amount equal to the difference between the stated minimum royalty amount and the actual royalties paid to Licensor.

3.4 Non-cash Consideration

If Licensee receives or anticipates receipt of non-cash consideration from Sales or Sublicenses, the manner in which Licensor will receive its compensation under the Agreement with respect to such non-cash consideration will be negotiated in good faith and timely agreed to by the Parties.

3.5 Litigation by Licensee

In the event Licensee brings an action seeking to invalidate or render unenforceable any Patent Rights:

(a) Licensee shall double the payments paid to Licensor during the pendency of such action. Moreover, should the outcome of such action determine that any claim of a patent challenged by the Licensee is both valid and infringed by a Licensed Product, Licensee shall pay triple the payment paid under the original Agreement;

(b) Licensee shall have no right to recoup any payments paid before or during the period of challenge;

(c) Licensee shall not pay royalties into any escrow or other similar account; and

(d) any dispute regarding the validity of any Patent Rights shall be litigated in the courts located in Bexar County Texas, and the parties agree not to challenge personal jurisdiction in that forum.

Licensee shall provide written notice to Licensor at least three (3) months prior to bringing an action seeking to invalidate or render unenforceable a Patent Right. Licensee shall include with such written notice an identification of all prior art it believes invalidates any claim of the Patent Right.

3.6 Reserved.

4. Reports and Plans

The reports specified in this Section 4 will be sent to Licensor's payment and reporting contact identified in Section 18 (Notices) of the Patent & Technology License Agreement. If Licensor requests to have information submitted in a particular format, Licensee will use reasonable efforts to comply with such request.

4.1 Quarterly Payment and Milestone Reports

On or before each Quarterly Payment Deadline, Licensee will deliver to Licensor a true and accurate report, certified by an officer of Licensee, giving such particulars of the business conducted by Licensee, its Affiliates and its Sublicensees (including copies of reports provided by Sublicensees and Affiliates to Licensee) during the preceding Contract Quarter under the Agreement as necessary for Licensor to account for Licensee's payments, including royalties, hereunder, even if no payments are due. The reports shall continue to be delivered after the termination or expiration of the Agreement until such time as all Licensed Products permitted to be Sold after termination or expiration have been Sold or destroyed. The report shall be in the format of **Exhibit B**, and shall include:

(a) The name of the Licensee, the Patent & Technology License Agreement number, and the period covered by the report;

(b) The name of any Affiliates and Sublicensees whose activities are also covered by the report;

(c) Identification of each Licensed Product and Licensed Service for which any royalty payments have become payable;

(d) Net Product Sales and Net Service Sales segregated on a product-by-product basis, and a country-by-country basis, or an affirmative statement that no Sales were made. The report shall also itemize the permitted deductions from the Gross Consideration used to arrive at the resulting Net Product Sales and Net Service Sales, on a product-by-product and country-by-country basis;

(e) The applicable royalty rate;

(f) An affirmative statement of whether any milestones with deadlines in that Contract Quarter under Section 2.4 and any milestones under Section 3.1(b) were met or not, and the resulting Milestone Fee payable;

(g) Non-Royalty Sublicensing Consideration received by Licensee segregated on a Sublicense-by-Sublicense basis, or an affirmative statement that none was received;

(h) If any consideration was received in currencies other than U.S. dollars, the report shall describe the currency exchange calculations; and

(i) Any changes in accounting methodologies used to account for and calculate the items included in the report since the previous report.

In addition, within 45 days of achieving each of the milestone obligations per Section 2.4(b) and within 30 days of achieving the milestones per Section 3.1(b), Licensee will submit a report to Licensor detailing the achievement of such milestone. For cash Milestone Fees, details of any calculation shall follow the requirements of reporting per this Section 4.1 (a) through (i).

4.2 Annual Written Progress Report and Commercialization Plan

Within 45 days following the end of each Contract Year, Licensee will deliver to Licensor a true and accurate signed written progress report, that summarizes (i) Licensee's efforts and accomplishments during the Contract Year to diligently commercialize Licensed Products and Licensed Services, and (ii) Licensee's development and commercialization plans with respect to Licensed Products and Licensed Services for the next Contract Year. The report shall also cover such activities by Affiliates and Sublicensees. The report shall be in the format of **Exhibit C** and shall contain the following information to the extent relevant to the activities under the Agreement:

(a) The name of the Licensee, the Patent & Technology License Agreement number, the names of any Affiliates and Sublicensees, and the products and services being developed and/or commercialized; and

(b) The progress toward completing and the plans for completing the applicable milestone events pursuant to Sections 2.4 and 3.1(b); and

(c) The research and development activities, including status and plans for obtaining any necessary Regulatory Approvals, performed during the past year, and the plans for research and development activities for the next year.

4.3 Government and Economic Development Reporting

If Licensor requests, Licensee will provide information for Licensor's Government and economic development reporting purposes, including the following:

(a) Number and geographic location of new full-time employees created during the past Contract Year; total number and geographic location of full-time employees of Licensee at the end of such Contract Year; and

(b) Dollar amount of new equity financing received by Licensee during the past Contract Year, and current capitalization, including number and class of outstanding securities; and

(c) Location and square footage of facilities; and

(d) Any information as required by any Government agreement, in order for Licensor to comply with obligations of any such agreement; and

(d) Other information required under Federal and state law.

This information shall be treated as Licensee's Confidential Information; provided that Licensor is entitled to combine such information with similar information from other Licensor licensees and publicly report such combined aggregate information, without identifying Licensee's separate specific applicable numbers. If and when Licensee has more than 200 full-time employees, then no further economic development reports will be required from Licensee.

4.4 Correspondence from a Regulatory Authority. Licensee agrees to provide Licensor with an electronic copy of any correspondence or communication regarding Licensed Product, Licensed Service, or Licensed Process from a Regulatory Authority to Licensee within thirty (30) days of Licensee's receipt of such correspondence or communication.

5. Payment, Records, and Audits

5.1 Payments

All amounts referred to in the Patent & Technology License Agreement are expressed in U.S. dollars without deductions for taxes, assessments, fees, or charges of any kind. Each payment will reference the agreement number set forth at the beginning of the Patent & Technology License Agreement. All payments to Licensor will be made in U.S. dollars by check or wire transfer (Licensee to pay all wire transfer fees) payable to the payee identified in Section 18 of the Patent & Technology License Agreement and sent to the payment and reporting contact in Section 18 (Notices) of the Patent & Technology License Agreement.

5.2 Sales Outside the U.S.

If any currency conversion shall be required in connection with the calculation of payments hereunder, such conversion shall be made using the rate used by Licensee for its financial reporting purposes in accordance with Generally Accepted Accounting Principles (or foreign equivalent) or, in the absence of such rate, using the average of the buying and selling exchange rate for conversion between the foreign currency and U.S. Dollars, for current transactions as reported in the New York City edition of *The Wall Street Journal* on the last business days of the Contract Quarter to which such payment pertains. Licensee may not make any tax withholdings from payments to Licensor, but Licensor agrees to supply to Licensee, upon written request, appropriate evidence from appropriate U.S. governmental agencies showing that Licensor is a resident of the United States of America for purposes of the U.S. income tax laws and is tax-exempt under such income tax laws.

5.3 Late Payments

Amounts that are not paid when due will accrue a late charge from the due date until paid, at a rate equal to 1.0% per month (or the maximum allowed by law, if less).

5.4 Records

For a period of six years after the Contract Quarter to which the records pertain, Licensee agrees that it and its Affiliates and Sublicensees will each keep complete and accurate records of their Sales, Net Product Sales, Net Service Sales, Milestone Fees, and Non-Royalty Sublicensing Consideration in sufficient detail to enable such payments to be determined and audited, including without limitation, general ledgers and sales registers.

5.5 Auditing

Licensee and its Affiliates will permit Licensor or its representatives, at Licensor's expense, to periodically examine books, ledgers, and records, including without limitation, general ledgers and sales registers, during regular business hours, at Licensee's or its Affiliate's place of business, on at least 30 days advance notice, to the extent necessary to verify any payment or report required under the Agreement. For each Sublicensee, Licensee shall obtain such audit rights for Licensor or itself. If Licensee obtains such audit rights for itself, it will promptly conduct an audit of the Sublicensee's records upon Licensor's request, and Licensee will furnish to Licensor a copy of the findings from such audit. No more than one audit of Licensee, each Affiliate, and each Sublicensee shall be conducted under this Section 5.5 in any calendar year. If any amounts due Licensor have been underpaid, then Licensee shall immediately pay Licensor the amount of such underpayment plus accrued interest due in accordance with Section 5.3. If the amount of underpayment is equal to or greater than 5% of the total amount due for the records so examined, Licensee will pay the cost of such audit. Such audits may, at Licensor's sole discretion, consist of a self-audit conducted by Licensee at Licensee's expense and certified in writing by an authorized officer of Licensee. All information examined pursuant to this Section 5.5 shall be deemed to be the Confidential Information of the Licensee.

6. Patent Expenses and Prosecution

6.1 Patent Expenses

Licensee shall pay for all past documented, out-of-pocket expenses incurred by Licensor for filing, prosecuting, defending and maintaining Patent Rights and related patent searches through the Effective Date of the Agreement, including those identified in Section 3.1(a) of the Patent & Technology License Agreement, and all such future expenses incurred by Licensor, for so long as, and in such countries as the Agreement remains in effect. Licensee will pay all patent expenses (except for the payment called for under Section 3.1(a)), including past expenses that have not been invoiced as of the date indicated in Section 3.1(a) of the Patent & Technology License Agreement and future expenses, within 30 days after Licensee's receipt of an invoice. At the election of Licensor, Licensee will either pay Prosecution Counsel directly for patent expenses or will reimburse Licensor for such patent expenses. Patent expense payment delinquencies (whether owed directly to Prosecution Counsel or to Licensor) will be considered a payment default under Section 7.3(a).

6.2 Direction of Prosecution

Licensor will confer with Licensee to develop a strategy for the prosecution and maintenance of Patent Rights. Licensor will request that copies of all documents prepared by the Prosecution Counsel for submission to governmental patent offices be provided to Licensee for review and comment prior to filing, to the extent practicable under the circumstances. At its discretion, Licensor may allow Licensee to instruct Prosecution Counsel directly, provided, that (a) Prosecution Counsel continues to provide copies of all documents to Licensor and allows Licensor opportunity for review and comment prior to filing; (b) Licensor will maintain final authority in all decisions regarding the prosecution and maintenance of the Patent Rights; (c) Licensor may revoke this authorization to instruct Prosecution Counsel directly at any time; and (d) the Prosecution Counsel remains counsel to the Licensor with an appropriate contract (and shall not jointly represent Licensee unless requested by Licensee and approved by Licensor, and an appropriate engagement letter and conflict waiver are in effect). If Licensee wishes to instruct Prosecution Counsel directly or change Prosecution Counsel, Licensee may request to do so by following the Licensor's procedures for such. Licensor reserves in its sole discretion the ability to change Prosecution Counsel and to approve or disapprove any requested changes by Licensee. The Parties agree that they share a common legal interest to get valid enforceable patents and that Licensee will maintain as privileged all information received pursuant to this Section. Notwithstanding the foregoing, the rights granted in this Section 6.2 shall remain with Licensee, and shall not extend to any Subsidiary, Sublicensee or Affiliate without prior written consent of University.

6.3 Ownership

All patent applications and patents will be in the name of Licensor (and any co-owner identified in Section 1 of the Patent & Technology License Agreement) and owned by Licensor (and such co-owner, if any). No payments due under the Agreement will be reduced as the result of co-ownership interests in the Patent Rights by Licensee or any other party.

6.4 Foreign Filings

In addition to the U.S., the Patent Rights shall, subject to applicable bar dates, be pursued in such foreign countries as Licensee so designates in writing to Licensor in sufficient time to reasonably enable the preparation of such additional filings, and in those foreign countries in which Licensor has filed applications prior to the Effective Date. If Licensee does not choose to pursue patent rights in a particular foreign country and Licensor chooses to do so, Licensee shall so notify Licensor and thereafter said patent application or patent shall no longer be included in the Patent Rights and Licensee shall have no further rights thereto. Licensor shall have the right to make alternative arrangements with Licensee for upfront payment of foreign patent expenses.

6.5 Withdrawal from Paying Patent Costs

If at any time Licensee wishes to cease paying for any costs for a particular Patent Right or for patent prosecution in a particular jurisdiction, Licensee must give Licensor at least 90 days prior written notice and Licensee will continue to be obligated to pay for the patent costs which reasonably accrue during said notice period. Thereafter, said patent application or patent shall no longer be included in the Patent Rights and Licensee shall have no further rights thereto.

6.6 U.S. Patent and Trademark Office Entity Size Status

Licensee represents that as of the Effective Date the entity size status of Licensee in accordance with the regulations of the U.S. Patent and Trademark Office is as set forth in Section 1 of the Patent & Technology License Agreement. Licensee will inform Licensor in writing on a timely basis of any change in its U.S. Patent and Trademark Office entity size status.

7. Term and Termination

7.1 Term

Unless earlier terminated as provided herein, the term of the Agreement will commence on the Effective Date and continue until the last date of expiration or termination of the Patent Rights, or if Technology Rights are licensed and no Patent Rights are applicable, for a term of 20 years.

7.2 Termination by Licensee

Licensee, at its option, may terminate the Agreement by providing Licensor written notice of intent to terminate, which such termination effective will be 90 days following receipt of such notice by Licensor.

7.3 Termination by Licensor

Licensor, at its option, may immediately terminate the Agreement, or any part of Licensed Subject Matter, or any part of Licensed Field, or any part of Territory, or the exclusive nature of the license grant, upon delivery of written notice to Licensee of Licensor's decision to terminate, if any of the following occur:

(a) Licensee becomes in arrears in any payments due under the Agreement, and Licensee fails to make the required payment within 30 days after delivery of written notice from Licensor; or

(b) Licensee is in breach of any non-payment provision of the Agreement, and does not cure such breach within 60 days after delivery of written notice from Licensor; or

(c) Licensor delivers notice to Licensee of three or more actual material breaches of the Agreement in any 12-month period, even in the event that Licensee cures such breaches in the allowed period; or

(d) Licensee or its Affiliate or Sublicensee initiates any proceeding or action to challenge the validity, enforceability, or scope of one or more of the Patent Rights, or assist a third party in pursuing such a proceeding or action; or

(e) Licensee breaches or defaults on any provision in any other agreement to which Licensor and Licensee are parties and Licensee does not cure such breach or default in the time allowed under such other agreement.

7.4 Other Conditions of Termination

The Agreement will terminate:

(a) Immediately without the necessity of any action being taken by Licensor or Licensee, (i) if Licensee becomes bankrupt or insolvent, or (ii) Licensee's Board of Directors elects to liquidate its assets or dissolve its business, or (iii) Licensee ceases its business operations, or (iv) Licensee makes an assignment for the benefit of creditors or (v) if the business or assets of Licensee are otherwise placed in the hands of a receiver, assignee or trustee, whether by voluntary act of Licensee or otherwise; or

(b) At any time by mutual written agreement between Licensee and Licensor.

7.5 Effect of Termination

If the Agreement is terminated for any reason:

(a) All rights and licenses of Sublicensees shall terminate upon termination of the Agreement; provided however, if the Sublicense Agreement is for all of the Licensed Field for all of the Territory, and the Sublicensee is in good standing and agrees in writing to assume all of the obligations of Licensee and provides Licensor with written notice thereof within 30 days after termination of the Agreement, then such Sublicense Agreement shall survive; and

(b) Licensee shall cease making, having made, distributing, having distributed, using, selling, offering to sell, leasing, loaning and importing any Licensed Products and performing Licensed Services by the effective date of termination; and

(c) Licensee shall tender payment of all accrued royalties and other payments due to Licensor as of the effective date of termination; and

(d) Nothing in the Agreement will be construed to release either Party from any obligation that matured prior to the effective date of termination; and

(e) The provisions of Sections 8 (Confidentiality), 9 (Infringement and Litigation), 11 (Representations and Disclaimers), 12 (Limit of Liability), 13 (Indemnification), 14 (Insurance), 17 (Use of Name), 18 (Notices), and 19 (General Provisions) will survive any termination or expiration of the Agreement. In addition, the provisions of Sections 3 (Compensation), 4.1 (Quarterly Payment and Milestone Reports), 5 (Payment, Records and Audits), and 6.1 (Patent Expenses) shall survive with respect to all activities and payment obligations accruing prior to the termination or expiration of the Agreement.

8. Confidentiality

8.1 Definition

"**Confidential Information**" means all information that is of a confidential and proprietary nature to Licensor or Licensee and provided by one Party to the other Party under the Agreement.

8.2 Protection and Marking

Licensor and Licensee each agree that all Confidential Information disclosed in tangible form, and marked "confidential" and forwarded to one by the other, or that would reasonably be recognized as confidential by a professional skilled in the applicable field, or if disclosed orally, is designated as confidential at the time of disclosure: (i) is to be held in strict confidence by the receiving Party, (ii) is to be used by and under authority of the receiving Party only as authorized in the Agreement, and (iii) shall not be disclosed by the receiving Party, its agents or employees without the prior written consent of the disclosing Party or as authorized in the Agreement. Licensee has the right to use and disclose Confidential Information of Licensor reasonably in connection with the exercise of its rights under the Agreement, including without limitation disclosing to Affiliates, Sublicensees, potential investors, acquirers, and others on a need to know basis, if such Confidential Information is provided under conditions which reasonably protect the confidentiality thereof. Each Party's obligation of confidence hereunder includes, without limitation, using at least the same degree of care with the disclosing Party's Confidential Information as it uses to protect its own Confidential Information, but always at least a reasonable degree of care.

8.3 Confidentiality of Terms of Agreement

Each Party agrees not to disclose to any third party the terms of the Agreement without the prior written consent of the other Party hereto, except each Party may disclose the terms of the Agreement: (a) to advisors, actual or potential Sublicensees, acquirers or investors, and others on a need to know basis, in each case, under appropriate confidentiality obligations substantially similar to those of this Section 8; and (b) to the extent necessary to comply with applicable laws and court orders (including, without limitation, The Texas Public Information Act, as may be amended from time to time, other open records laws, decisions and rulings, and securities laws, regulations and guidance). If the Agreement is not for all fields of use, then Licensor may disclose the Licensed Field or Excluded Field to other potential third party licensees. Notwithstanding the foregoing, the existence of the Agreement shall not be considered Confidential Information.

8.4 Disclosure Required by Court Order or Law

If the receiving Party is required to disclose Confidential Information of another Party hereto, or any terms of the Agreement, pursuant to the order or requirement of a court, administrative agency, or other governmental body or applicable law, the receiving Party may disclose such Confidential Information or terms to the extent required, provided that the receiving Party shall use reasonable efforts to provide the disclosing Party with reasonable advance notice thereof to enable the disclosing Party to seek a protective order and otherwise seek to prevent such disclosure. To the extent that Confidential Information so disclosed does not become part of the public domain by virtue of such disclosure, it shall remain Confidential Information protected pursuant to Section 8.

8.5 Copies

Each Party agrees not to copy or record any of the Confidential Information of the other Party, except as reasonably necessary to exercise its rights or perform its obligations under the Agreement, and for archival and legal purposes.

8.6 Continuing Obligations

Subject to the exclusions listed in Section 8.7, the Parties' confidentiality obligations under the Agreement will survive termination of the Agreement and will continue for a period of five years thereafter.

8.7 Exclusions

Information shall not be considered Confidential Information of a disclosing Party under the Agreement to the extent that the receiving Party can establish by competent written proof that such information:

(a) Was in the public domain at the time of disclosure; or

(b) Later became part of the public domain through no act or omission of the recipient Party, its employees, agents, successors or assigns in breach of the Agreement; or

(c) Was lawfully disclosed to the recipient Party by a third party having the right to disclose it not under an obligation of confidentiality; or

(d) Was already known by the recipient Party at the time of disclosure; or

(e) Was independently developed by the recipient Party without use of the disclosing Party's Confidential Information.

8.8 Copyright Notice

The placement of a copyright notice on any Confidential Information will not be construed to mean that such information has been published and will not release the other Party from its obligation of confidentiality hereunder

9. Infringement and Litigation

9.1 Notification

If either Licensor's designated office for technology commercialization or Licensee becomes aware of any infringement or potential infringement of Patent Rights, each Party shall promptly notify the other of such in writing.

9.2 Licensee's Enforcement Rights

Licensee shall enforce the Patent Rights against any infringement by a third party. Licensee shall be responsible for payment of all fees and expenses associated with such enforcement incurred by Licensee and incurred by Licensor in providing cooperation or joining as a party as provided in Section 9.4. Any monetary recovery for actual damages or punitive damages, in excess of Licensee's documented, third-party expenses in enforcing the Patent Rights and amounts actually reimbursed by Licensee to Licensor under this Section 9.2 shall be shared by Licensee with Licensor in the same manner as Non-Royalty Sublicensing Consideration.

9.3 Licensor's Enforcement Rights

If Licensee does not file suit within six months after a written request by Licensor to initiate an infringement action, then Licensor shall have the right, at its sole discretion, to bring suit to enforce any Patent Right licensed hereunder against the infringing activities, with Licensor retaining all recoveries from such enforcement. If Licensor pursues such infringement action, Licensor may, as part of the resolution of such efforts, grant non-exclusive license rights to the alleged infringer notwithstanding Licensee's exclusive license rights.

9.4 Cooperation between Licensor and Licensee

In any infringement suit or dispute, the Parties agree to cooperate fully with each other. At the request of the Party bringing suit, the other Party will permit reasonable access after reasonable advance notice to all relevant personnel, records, papers, information, samples, specimens, etc., during regular business hours.

If it is necessary to name Licensor as a party in such action, then Licensee must first obtain Licensor's prior written permission, which permission shall not be unreasonably withheld, provided that Licensor shall have reasonable prior input on choice of counsel on any matter where such counsel represents Licensor, and Licensee and such counsel agree to follow all required procedures of the Texas Attorney General regarding retention of outside counsel for state entities.

10. Export Compliance

Licensee understands that the Arms Export Control Act (AECA), including its implementing International Traffic In Arms Regulations (ITAR), and the Export Administration Act (EAA), including its Export Administration Regulations (EAR), are some (but not all) of the laws and regulations that comprise the U.S. export laws and regulations. Licensee further understands that the U.S. export laws and regulations include (but are not limited to): (a) ITAR and EAR product/service/data-specific requirements; (b) ITAR and EAR ultimate destination-specific requirements; (c) ITAR and EAR end user-specific requirements; (d) Foreign Corrupt Practices Act; and (e) anti-boycott laws and regulations. Licensee will comply with all then-current applicable export laws and regulations of the U.S. Government (and other applicable U.S. laws and regulations) pertaining to the Licensed Products and Licensed Services (including any associated products, items, articles, computer software, media, services, technical data, and other information). Licensee certifies that it will not, directly or indirectly, export (including any deemed export), nor re-export (including any deemed re-export) the Licensed Products and Licensed Services (including any associated products, items, articles, computer software, media, services, technical data, and other information) in violation of applicable U.S. laws and regulations. Licensee will include a provision in its agreements, substantially similar to this Section 10, with its Sublicensees, third party wholesalers and distributors, and physicians, hospitals or other healthcare providers who purchase a Licensed Product, requiring that these parties comply with all then-current applicable U.S. export laws and regulations and other applicable U.S. laws and regulations.

11. Representations and Disclaimers

11.1 Licensor Representations

Except for the rights, if any, of the Government as set forth in Section 11.2, Licensor represents and warrants to Licensee that to the knowledge of Licensor's designated office for technology commercialization (i) Licensor is the owner or agent of the entire right, title, and interest in and to Patent Rights (other than the right, title and interest of any joint owner identified in Section 1 of the Patent & Technology License Agreement), (ii) Licensor has the right to grant licenses hereunder, and (iii) Licensor has not knowingly granted and will not knowingly grant licenses or other rights under the Patent Rights that are in conflict with the terms and conditions in the Agreement.

11.2 Government Rights

Licensee understands that Licensed Subject Matter may have been developed under a funding agreement with Government and, if so, that Government may have certain rights relative thereto. The Agreement is made subject to the Government's rights under any such agreement and under any applicable Government law or regulation. To the extent that there is a conflict between any such agreement, such applicable law or regulation and the Agreement, the terms of such Government agreement, and applicable law or regulation, shall prevail. Licensee agrees that, to the extent required by U.S. laws and regulations, Licensed Products used or Sold in the U.S. will be manufactured substantially in the U.S., unless a written waiver is obtained in advance from the U.S. Government.

11.3 Licensor Disclaimers

EXCEPT AS SPECIFICALLY SET FORTH IN SECTION 11.1, LICENSEE UNDERSTANDS AND AGREES THAT LICENSOR MAKES NO REPRESENTATIONS OR WARRANTIES OF ANY KIND, EXPRESS OR IMPLIED, INCLUDING, WITHOUT LIMITATION, AS TO THE LICENSED PRODUCTS OR LICENSED SERVICES, OR AS TO THE OPERABILITY OR FITNESS FOR ANY USE OR PARTICULAR PURPOSE, MERCHANTABILITY, SAFETY, EFFICACY, APPROVABILITY BY REGULATORY AUTHORITIES, TIME AND COST OF DEVELOPMENT, PATENTABILITY, AND/OR BREADTH OF PATENT RIGHTS. LICENSOR MAKES NO REPRESENTATION AS TO WHETHER ANY PATENT WITHIN PATENT RIGHTS IS VALID, OR AS TO WHETHER THERE ARE ANY PATENTS NOW HELD, OR WHICH WILL BE HELD, BY OTHERS OR BY LICENSOR THAT MIGHT BE REQUIRED FOR USE OF PATENT RIGHTS IN ANY FIELD. NOTHING IN THE AGREEMENT WILL BE CONSTRUED AS CONFERRING BY IMPLICATION, ESTOPPEL OR OTHERWISE ANY LICENSE OR RIGHTS TO ANY PATENTS OR TECHNOLOGY OF LICENSOR OTHER THAN THE PATENT RIGHTS IN THE LICENSED FIELD, WHETHER SUCH PATENTS ARE DOMINANT OR SUBORDINATE TO THE PATENT RIGHTS, OR THE TECHNOLOGY RIGHTS IN THE LICENSED FIELD SPECIFICALLY DESCRIBED HEREIN

11.4 Licensee Representation

By execution of the Agreement, Licensee represents, acknowledges, covenants and agrees (a) that Licensee has not been induced in any way by Licensor or its employees to enter into the Agreement, and (b) that Licensee has been given an opportunity to conduct sufficient due diligence with respect to all items and issues pertaining to this Section 11 (Representations and Disclaimers) and all other matters pertaining to the Agreement; and (c) that Licensee has adequate knowledge and expertise, or has utilized knowledgeable and expert consultants, to adequately conduct the due diligence, and (d) that Licensee accepts all risks inherent herein. Licensee represents that it is a duly organized, validly existing entity of the form indicated in Section 1 of the Patent & Technology License Agreement, and is in good standing under the laws of its jurisdiction of organization as indicated in Section 1 of the Patent & Technology License Agreement, and has all necessary corporate or other appropriate power and authority to execute, deliver and perform its obligations hereunder.

12. Limit of Liability

IN NO EVENT SHALL LICENSOR, THE UNIVERSITY SYSTEM IT GOVERNS, ITS MEMBER INSTITUTIONS, INVENTORS, REGENTS, OFFICERS, EMPLOYEES, STUDENTS, AGENTS OR AFFILIATED ENTERPRISES, BE LIABLE FOR ANY INDIRECT, SPECIAL, CONSEQUENTIAL, INCIDENTAL, EXEMPLARY, OR PUNITIVE DAMAGES (INCLUDING, WITHOUT LIMITATION, DAMAGES FOR LOSS OF PROFITS OR REVENUE) ARISING OUT OF OR IN CONNECTION WITH THE AGREEMENT OR ITS SUBJECT MATTER, REGARDLESS OF WHETHER ANY SUCH PARTY KNOWS OR SHOULD KNOW OF THE POSSIBILITY OF SUCH DAMAGES. OTHER THAN FOR CLAIMS AGAINST LICENSEE FOR INDEMNIFICATION (SECTION 13) OR FOR MISUSE OR MISAPPROPRIATION OR INFRINGEMENT OF LICENSOR'S INTELLECTUAL PROPERTY RIGHTS, LICENSEE WILL NOT BE LIABLE TO LICENSOR FOR ANY INDIRECT, SPECIAL, CONSEQUENTIAL OR PUNITIVE DAMAGES (INCLUDING, WITHOUT LIMITATION, DAMAGES FOR LOSS OF PROFITS OR REVENUE) ARISING OUT OF OR IN CONNECTION WITH THE AGREEMENT OR ITS SUBJECT MATTER, REGARDLESS OF WHETHER LICENSEE KNOWS OR SHOULD HAVE KNOWN OF THE POSSIBILITY OF SUCH DAMAGES.

13. Indemnification

13.1 Indemnification Obligation

Subject to Section 13.2, Licensee agrees to hold harmless, defend and indemnify Licensor, the university system it governs, its member institutions, its Regents, officers, employees, students and agents ("Indemnified Parties") from and against any liabilities, damages, causes of action, suits, judgments, liens, penalties, fines, losses, costs and expenses (including, without limitation, reasonable attorneys' fees and other expenses of litigation) (collectively "Liabilities") resulting from claims or demands brought by third parties against an Indemnified Party on account of any injury or death of persons, damage to property, or any other damage or loss arising out of or in connection with the Agreement or the exercise or practice by or under authority of Licensee, its Affiliates or their Sublicensees, or third party wholesalers or distributors, or physicians, hospitals or other healthcare providers who purchase a Licensed Product, of the rights granted hereunder.

13.2 Conditions of Indemnification

Licensee shall have no responsibility or obligation under Section 13.1 for any Liabilities to the extent caused by the gross negligence or willful misconduct by Licensor. Obligations to indemnify, and hold harmless under Section 13.1 are subject to: (a) to the extent authorized by the Texas Constitution and the laws of the State of Texas, and subject to the statutory duties of the Texas Attorney General, the Indemnified Party giving Licensee control of the defense and settlement of the claim and demand; and (b) to the extent authorized by the Texas Constitution and the laws of the State of Texas and subject to statutory duties of the Texas Attorney General, the Indemnified Party providing assistance reasonably requested by Licensee, at Licensee's expense.

14. Insurance

14.1 Insurance Requirements

Prior to any Licensed Product being used or Sold (including for the purpose of obtaining Regulatory Approval), and prior to any Licensed Service being performed by Licensee, an Affiliate, or by a Sublicensee, and for a period of five years after the Agreement expires or is terminated, Licensee shall, at its sole cost and expense, procure and maintain commercial general liability insurance in commercially reasonable and appropriate amounts for the Licensed Product being used or Sold or the Licensed Service being performed. Licensee shall use commercially reasonable efforts to have Licensor, the university system it governs, its member institutions, Regents, officers, employees, and Inventors named as additional insureds. Such commercial general liability insurance shall provide, without limitation: (i) product liability coverage; (ii) broad form contractual liability coverage for Licensee's indemnification under the Agreement; and (iii) coverage for litigation costs.

14.2 Evidence of Insurance and Notice of Changes

Upon request by Licensor, Licensee shall provide Licensor with written evidence of such insurance. Additionally, Licensee shall provide Licensor with written notice of at least 60 days prior to Licensee cancelling, not renewing, or materially changing such insurance.

15. Assignment

The Agreement may not be assigned by Licensee without the prior written consent of Licensor, which consent will not be unreasonably withheld. A merger or other transaction in which the equity holders of Licensee prior to such event hold less than a majority of the equity of the surviving or acquiring entity shall be considered an assignment of the Agreement. For any permitted assignment to be effective, (a) Licensee must be in good standing under this Agreement, (b) the Licensee must pay Licensor the assignment fee pursuant to Section 3.1(e), and (c) the assignee must assume in writing (a copy of which shall be promptly provided to Licensor) all of Licensee's interests, rights, duties and obligations under the Agreement and agree to comply with all terms and conditions of the Agreement as if assignee were an original Party to the Agreement.

16. Governmental Markings

16.1 Patent Markings

Licensee agrees that all Licensed Products Sold by Licensee, Affiliates, or Sublicensees will be legibly marked with the number of any applicable patent(s) licensed hereunder as part of the Patent Rights in accordance with each country's patent marking laws, including Title 35, U.S. Code, or if such marking is not practicable, shall so mark the accompanying outer box or product insert for Licensed Products accordingly. Licensee will not engage in false marketing of Licensed Products and Licensee will be responsible for any damages and penalties imposed for false marketing claims.

16.2 Governmental Approvals and Marketing of Licensed Products and or Licensed Services

Licensee will be responsible for obtaining all necessary governmental approvals for the development, production, distribution, advertising, Sale, and use of any Licensed Product or performance of any Licensed Service, at Licensee's expense, including, without limitation, any safety studies. Licensee will have sole responsibility for any warning labels, packaging and instructions as to the use and the quality control for any Licensed Product or Licensed Service.

16.3 Foreign Registration and Laws

Licensee agrees to register the Agreement with any foreign governmental agency that requires such registration; and Licensee will pay all costs and legal fees in connection with such registration. Licensee is responsible for compliance with all foreign laws affecting the Agreement or the Sale of Licensed Products and Licensed Services to the extent there is no conflict with United States law, in which case United States law will control.

17. Use of Name

Licensee will not use the name, trademarks or other marks of Licensor (or the name of the university system it governs, its member institutions, any of its Regents or employees) without the advance written consent of Licensor. Licensor may use Licensee's name and logo for annual reports, brochures, website and internal reports without prior consent.

18. Notices

Any notice or other communication of the Parties required or permitted to be given or made under the Agreement will be in writing and will be deemed effective when sent in a manner that provides confirmation or acknowledgement of delivery and received at the address set forth in Section 18 of the Patent & Technology License Agreement (or as changed by written notice pursuant to this Section 18). Notices required under the Agreement may be delivered via E-mail provided such notice is confirmed in writing as indicated.

Notices shall be provided to each Party as specified in the "Contact for Notice" address set forth in Section 18 of the Patent & Technology License Agreement. Each Party shall update the other Party in writing with any changes in such contact information.

19. General Provisions

19.1 Binding Effect

The Agreement is binding upon and inures to the benefit of the Parties hereto, their respective executors, administrators, heirs, permitted assigns, and permitted successors in interest.

19.2 Construction of Agreement

Headings are included for convenience only and will not be used to construe the Agreement. The Parties acknowledge and agree that both Parties substantially participated in negotiating the provisions of the Agreement; therefore, both Parties agree that any ambiguity in the Agreement shall not be construed more favorably toward one Party than the other Party, regardless of which Party primarily drafted the Agreement.

19.3 Counterparts and Signatures

The Agreement may be executed in multiple counterparts, each of which shall be deemed an original, but all of which taken together shall constitute one and the same instrument. A Party may evidence its execution and delivery of the Agreement by transmission of a signed copy of the Agreement via facsimile or email. In such event, the Party shall promptly provide the original signature page(s) to the other Party.

19.4 Compliance with Laws

Licensee will comply with all applicable federal, state and local laws and regulations, including, without limitation, all export laws and regulations.

19.5 Governing Law

The Agreement will be construed and enforced in accordance with laws of the U.S. with respect to patent law and the State of Texas for all other aspects of this Agreement, without regard to choice of law and conflicts of law principles.

19.6 Modification

Any modification of the Agreement will be effective only if it is in writing and signed by duly authorized representatives of both Parties. No modification will be made by email communications.

19.7 Severability

If any provision hereof is held to be invalid, illegal or unenforceable in any jurisdiction, the Parties hereto shall negotiate in good faith a valid, legal and enforceable substitute provision that most nearly reflects the original intent of the Parties, and all other provisions hereof shall remain in full force and effect in such jurisdiction and shall be construed in order to carry out the intentions of the Parties hereto as nearly as may be possible. Such invalidity, illegality or unenforceability shall not affect the validity, legality or enforceability of such other provisions in any other jurisdiction, so long as the essential essence of the Agreement remains enforceable.

19.8 Third Party Beneficiaries

Nothing in the Agreement, express or implied, is intended to confer any benefits, rights or remedies on any entity, other than the Parties and their permitted successors and assigns. However, if there is a joint owner of any Patent Rights identified in Section 1 of the Patent & Technology License Agreement (other than Licensee), then Licensee hereby agrees that the following provisions of these Terms and Conditions extend to the benefit of the co-owner identified therein (excluding the Licensee to the extent it is a co-owner) as if such co-owner was identified in each reference to the Licensor: the retained rights under clause (b) of Section 2.1; Section 11.3 (Licensor Disclaimers); Section 12 (Limitation of Liability); Section 13 (Indemnification); Section 14.1 (Insurance Requirements); Section 17 (Use of Name); and Section 19.10 (Sovereign Immunity, if applicable).

19.9 Waiver

Neither Party will be deemed to have waived any of its rights under the Agreement unless the waiver is in writing and signed by such Party. No delay or omission of a Party in exercising or enforcing a right or remedy under the Agreement shall operate as a waiver thereof.

19.10 Sovereign Immunity

Nothing in the Agreement shall be deemed or treated as any waiver of Licensor's sovereign immunity.

19.11 Entire Agreement

The Agreement constitutes the entire Agreement between the Parties regarding the subject matter hereof, and supersedes all prior written or verbal agreements, representations and understandings relative to such matters.

19.12 Claims Against Licensor for Breach of Agreement

Licensee acknowledges that any claim for breach of the Agreement asserted by Licensee against Licensor shall be subject to Chapter 2260 of the Texas Government Code and that the process provided therein shall be Licensee's sole and exclusive process for seeking a remedy for any and all alleged breaches of the Agreement by Licensor or the State of Texas.

19.13 Grant of Security Interest

Licensee hereby grants to Licensor a security interest in and to Licensee's rights under the Patent & Technology License Agreement, as collateral security for the payment by Licensee of any and all sums which may be owed from time to time by Licensee to Licensor. Licensor shall have all rights of a secured party as specified in the Texas Uniform Commercial Code relative to this security interest and the enforcement thereof. Licensee hereby authorizes Licensor to file with the appropriate governmental agencies appropriate UCC-1 financing statements to evidence this security interest.

19.14 Jurisdiction and Venue

The parties hereby irrevocably submit to the exclusive jurisdiction of a court of competent jurisdiction in Bexar County Texas, and, by execution and delivery of this Agreement, each party (a) accepts, generally and unconditionally, the jurisdiction of such court and any related appellate court, and (b) irrevocably waives any objection it may now or hereafter have as to the venue of any such suit, action or proceeding brought in such court or that such court is an inconvenient forum.

-- END OF EXHIBIT A --

EXHIBIT B
ROYALTY REPORT

Required Royalty Report information includes:

- The applicable OTC case reference number(s): (e.g., YYYY.XXX.HSCS.LA-1)
- Reporting Period
- Catalog number and units Sold of each Licensed Product (domestic and foreign)
- Gross Sales per catalog number per country
- Total gross Sales
- Itemized deductions from gross Sales
- Total Net Sales
- Running Royalty rate and associated calculations
- Gross earned royalty
- Adjustments for Minimum Royalty and other creditable payments made by Licensee to University
- Net earned royalty due to University

Example:

WidgetCo Inc. Royalty Report
For Reporting Period ended December 31, 2015
OTC Case Number: 2010.000.LA1.HSCS

Catalog Number	Product Name	Country	Units Sold	Gross Sales (US$)
1	A	US	250	62,500
1	A	UK	32	16,500
1	A	France	25	15,625
2	B	US	0	0
3	C	US	57	57,125
4	D	US	12	1,500

Total Gross Sales:	**$**	**153,250**
Less - Deductions		
Returns		7,000
Total Net Sales:	**$**	**146,250**
Running Royalty:		
Royalty rate		10%
Royalty due		14,625
Less - Creditable Payments		
Minimum Royalty		10,000
Net Royalty Due	**$**	**4,625**

-- END OF EXHIBIT B --

EXHIBIT C

***COMPANY*, INC.**
TECHNOLOGY DEVELOPMENT REPORT FOR *PRODUCT*
For Calendar Quarter Ended MM/YYYY

	DESCRIPTION OF ACTIVITY **Note: Content of Licensee's TDR form will follow from Licensee's Product Development Plan (PDP).**	**Estimated Start**	**Estimated Finish**	**Amount Budgeted for Current Period**	**Amount Spent During Current Period**	**Progress to Date/Commentary NOTE: Achievement of any of the Milestones listed in Patent License Agreement § 2.4 (Diligence Milestones) during the Reporting Period must be explicitly noted in this Report.**
1	**PROJECT INITIATION**					
	Due diligence	Jun-08	Aug-08	$3,000	$2,800	
2	**EARLY PRODUCT DEVELOPMENT**					
	Manufacture Investigational Product for Testing	Sep-08	Oct-08			
3	**INITIATE PRE CLINICAL DEVELOPMENT PROGRAM**					
	Basic safety study	Jan-09	Feb-09			
4	**GLP-Compliant IND/PMA/BLA-ENABLING STUDIES**					
	GLP Toxicology study	Oct-09	Jan-10			
5	**IND/PMA/BLA PREPARATION**					
	Write all Sections					
	Sumbit IND					
	FDA review of IND					
6	**CLINICAL DEVELOPMENT PROGRAM**					
6a	Phase I clinical study	Mar-10	Mar-11			
	Phase I Trial Activities					
	Phase I Clinical Trial Report					
6b	Phase II clinical studies	May-11	Feb-13			
	Phase II Trial Activities					
	Phase II Clinical Trial Report	Mar-13				
6c	New Drug Application (NDA)					
	File NDA with FDA	Apr-13				
	FDA Review					
FDA APPROVAL OF PRODUCT		***Dec-13***				
CUMULATIVE AMOUNT BUDGETED AND SPENT ON SUBJECT MATTER R&D:				**$3,000**	**$2,800**	

-- END OF EXHIBIT C --

Exhibit 10.2

C&M Comments 1-31-23

CO-DEVELOPMENT AGREEMENT
AND MATERIAL TRANSFER FOR COLLABORATIVE RESEARCH

This Co-Development Agreement (the "**Agreement**") is made between Blue Water Vaccines Inc. ("**BWV")** located at 201 E Fifth Street, Suite 1900, Cincinnati, OH 45202 and AbVacc, Inc. ("**ABVACC**") located at 4 Research Court., Suite 310, Rockville, MD, 20878, USA (each of the ABVACC and BWV, a "**Party**" and together, the "**Parties**").

Collectively, the Parties will share material(s) ("**Material**") and/or their information related to Material ("**Information**") for research on evaluation of Norovirus S and P particles as platform for expression of heterologous vaccine antigens including, but not limited to, those described further in Appendix A. For Material and Information, "**Provider**" refers to either Party when acting as a provider and "**Recipient**" refers to either Party when acting as a recipient.

For and in consideration of, and conditioned on, the covenants stated herein, and for other good and valuable consideration, the receipt and sufficiency of which the Parties hereby acknowledge, the Parties agree as follows:

1. **Purpose**. The purpose of this Agreement is to establish the terms for conducting research aimed at co-development of specific vaccine candidates using the Norovirus nanoparticle platform ("**Co-Development Project**"), govern the sharing and use of Material and/or Information by the Parties for the Co-Development Project. If the Parties decide to collaborate on additional research using Material, then a mutually acceptable written amendment to this Agreement or new agreement, which describes the additional research project, will be required. Each Party will endeavor to achieve the objectives of the Co-Development Project described in Appendix A. However, the Parties understand and acknowledge that, due to the nature of the research process, the objectives of the Co-Development Project may not be achieved and thus will not be interpreted as any type of warranty or deliverable. BWV and ABVACC acknowledge and agree that both Parties will endeavor to conduct the Co-Development Project in a timely manner but may experience a change in research priorities due to its mission. In the event of such a change in priorities that will significantly delay the Co-Development Project, BWV and ABVACC will agree to suspend, change research project details, modify the research project, or terminate the research project through written or email notification.

2. **Use/Non-use and Disposition of BWV's Material**. ABVACC agrees that Material and/or Information it receives from BWV will be used only for the Co-Development Project and for no other purpose whatsoever. ABVACC further agrees not to transfer BWV's Material and/or Information to any other Party without advance written approval from an authorized representative of BWV; if approved by BWV, any transfer to and use by the transferee(s) of BWV's Material and/or Information will be subject to the restrictions and obligations imposed by this Agreement. Notwithstanding any other provision of this Agreement, BWV agrees that Material and/or Information it provides to ABVACC under this Agreement may be used by one or more of Integrated BioTherapeutics LLC's ("**IBT**") laboratories, its on-site scientific/technical contract personnel, or contract testing laboratories solely for the Co-Development Project. When the Co-Development Project is complete or upon expiration or early termination of this Agreement, whichever occurs sooner, any remaining Material received from BWV will be retained in IBT's facility or handled in another manner as agreed by the Parties.

3. **Use/Non-use and Disposition of ABVACC's Material**. BWV agrees that Material and/or Information it receives from ABVACC will be used only for the Co-Development Project and for no other purpose whatsoever. BWV further agrees not to transfer ABVACC's Material and/or Information to any other Party without advance written approval from an authorized representative of ABVACC; if approved by ABVACC, any transfer to and use by the transferee(s) of ABVACC's Material and/or Information will be subject to the restrictions and obligations imposed by this Agreement. Notwithstanding any other provision of this Agreement, ABVACC agrees that Material and/or Information it provides to BWV under this Agreement may be used by one or more of BWV laboratories, its on-site scientific/technical contract personnel, or contract testing laboratories solely for the Research Project. When the Co-Development Project is complete or upon expiration or early termination of this Agreement, whichever occurs sooner, any remaining Material received from ABVACC will be retained in BWV's facility or handled in another manner as agreed by the Parties.

4. **Intellectual Property (IP)**

Background IP. Each Party retains all rights, title and interest in and to, including any and all intellectual property rights, its Material and Information or potential rights, such as issued patents, patent applications or invention disclosures, which exist prior to execution of this Agreement ("**Background IP**") or developed independent of this Agreement without use of the Material and/or Information ("**Party IP**"). Each Party hereby grants to the other Party a non-exclusive, fully paid, worldwide, non-transferable, limited license to use Background IP (and shall obtain the same license/consent as required from any third-party from whom the Party derives rights to the extent such rights are licensed to a Party as of the Effective Date) solely for the Co-Development Project. Neither Party obtains rights to the other Party's Background IP under this Agreement except for the purpose of conducting the Co-Development Project.

Co-Development Agreement (CDA) Inventions. Ownership of any invention patentable under U.S. patent law which is conceived or first actually reduced to practice under this Agreement ("**CDA Invention**") will follow inventorship in accordance with U.S. patent law, such that inventions made solely by the employees or contractors of one Party shall belong solely to that Party. Any CDA Invention made jointly by employees and/or contractors of the Parties under this Agreement ("**Joint CDA Invention**") will be owned jointly by the Parties and the Parties will, by separate agreement or operation of law, require their employee and/or contractor co-inventors to assign their rights in the Joint CDA Invention to their employing organization or the Party that engages such contractors. The Parties acknowledge and agree that any Joint CDA Invention is jointly developed by the Parties and each Party shall have a one-half undivided interest in the whole of the Joint CDA Invention and shall have full rights of use and ownership of such Joint CDA Invention.

Each Party agrees to inform the other Party, in confidence, of any CDA Invention arising under this Agreement. ABVACC agrees to grant BWV an option for an exclusive commercialization license to their rights to any patent application claiming a CDA Invention made in whole or in part by an ABVACC employee(s) or contractor(s) that is directly related to and requires the use of BWV's Material, on the terms set forth on Annex B hereto. Unless extended in writing, BWV's license option must be exercised within six (6) months of being informed of the invention disclosure on the relevant CDA Invention(s) by providing written notice to BWV.

5. **Confidential Information**

General. Each Party agrees to maintain in confidence for a period of three (3) years following the expiration or early termination of this Agreement, any proprietary, non-public confidential business information or unpublished scientific/technical information which the other Party has provided to the other Party ("**Confidential Information**"). Neither Party may disclose the other Party's Confidential Information to others without the specific written permission, in advance, of the other Party, unless required to disclose by law, regulation or court order. In any event, the Parties agree to promptly communicate to each other any third-party request for the other Party's Confidential Information.

Exceptions. Neither Party incurs an obligation of confidentiality with respect to information which (a) is known to the receiving Party before its receipt, and not already under any obligation of confidentiality to the disclosing Party; or (b) is or becomes publicly known without any breach of this Agreement or of any other obligation to keep it confidential; or (c) is obtained by the receiving Party from a third party under circumstances where the receiving Party has no reason to believe that there has been a breach of an obligation of confidentiality owed to the disclosing Party; or (d) is independently developed by the receiving Party; or (e) is approved for release in writing by an authorized representative of the disclosing Party. For the avoidance of doubt, this **Section 5** will not apply to any Confidential Information that is required to be disclosed by law or judicial order or other legal requirements; provided, that to the extent legally permitted and practicable under the circumstances prior written notice of such required disclosure is furnished to the disclosing Party as soon as practicable in order to afford the disclosing Party an opportunity to seek a protective order and that if such order cannot be obtained disclosure may be made without liability.

Each Party may retain one (1) copy of the other Party's Confidential Information in a secure location for archival purposes following the expiration or early termination of this Agreement. In addition, a Party (i) will not be required to destroy electronic versions of Confidential Information from back-up, archival electronic storage made in the ordinary course of business, and (ii) may retain a limited number of copies of the Confidential Information for its legal files for compliance and regulatory purposes, including to the extent required by law, rule or regulation.

6. **Joint Development Committee.** Within thirty (30) calendar days after the Effective Date, the Parties will determine a mutually agreeable number of participants for and appoint their respective representatives to a joint development committee to manage the development strategies, plans and budgets for Co-development Project (the "**Joint Development Committee**" or "**JDC**"). Each party shall be entitled to appoint an equal number of representatives to the JDC.

7. **CDA Technical Data**. All research data and other recorded information, regardless of the form or method of recording, first produced in the conduct of the Co-Development Project, is referred to herein as "**CDA Technical Data**." The Parties understand and agree that the CDA Technical Data is being obtained through *in vitro* experiments and exploratory *in vivo* research studies in mice. The CDA Technical Data shall be used and disclosed in a manner that does not jeopardize the patent or publication rights of either Party.

8. **Reporting**. Each Party agrees to report in a timely manner and in confidence all CDA Technical Data and all CDA Inventions to the other Party. BWV understands and acknowledges that ABVACC may be required to report the results of its research activities, including CDA Technical Data and CDA Inventions. Accordingly, the Parties agree to cooperate in a timely manner on writing any reports due in connection with this Agreement. Subject to any mandatory reporting requirements as described above, the Parties agree to keep CDA Technical Data and CDA Inventions confidential until patent applications claiming CDA Inventions have been filed or until publications and/or presentations concerning the Co-Development Project are made in accordance with Paragraph 10. If no patent applications are filed, or no publications or presentations are made in accordance with Paragraph 10, each Party agrees that, with respect to public disclosure, any CDA Technical Data and supporting data generated solely by the other Party and not publicly disclosed will become Confidential Information of the other Party subject to Paragraph 5, provided, however, that each Party retains the rights set forth in Paragraph 7 to such CDA Technical Data.

9. **Regulatory Filings**. The CDA Technical Data may be submitted to the U.S. Food and Drug Administration or equivalent foreign regulatory agencies in support of Investigational New Drug ("**IND**"), or equivalent, applications. In addition, each Party will provide the other party at least 20 calendar days prior written notice of the intention to file any CDA Technical Data with the U.S. Food and Drug Administration or equivalent foreign regulatory agencies as permitted by this Agreement.

10. **Research Publications and Presentations**

    General. It is understood that the Co-Development Project may result in new scientific knowledge that may be suitable for publication in peer-reviewed scientific journals and/or presented at scientific meetings ("**Research Results**"), so publication and/or presentation of the Research Results is of prime interest to ABVACC and BWV. It is anticipated that the Research Results will be published jointly by the Parties. In all such oral or written publications by BWV, or jointly, concerning the Co-Development Project ("**Research Publication**") each Party's contribution will be expressly noted, by either acknowledgment or co-authorship, as appropriate, with authorship being determined in accordance with the policies and customs for authorship of scientific publications. It is understood that the Research Results are based upon the CDA Technical Data and therefore the Research Publications may disclose any of the CDA Technical Data.

    Publication Review. For the purpose of restricting any disclosure of the other Party's Confidential Information, the publishing Party or, in the case of joint Research Publications, the lead publishing Party ("**Publishing Party**") agrees to send its proposed Research Publication for review and comment by the other Party ("Reviewing Party"). The Reviewing Party agrees to send its comments or suggested revisions to the proposed Research Publication to the Publishing Party within thirty (30) calendar days of receipt of the proposed Research Publication. It is agreed that if the Reviewing Party does not respond by the end of the thirty (30) calendar day review period, the Publishing Party may proceed with its proposed Research Publication; provided, however, if BWV is the Reviewing Party and has not responded by the end of the thirty (30) day review period, the Publishing Party agrees to provide written notification to BWV point of contact for publications below. Upon the Reviewing Party's written request received within thirty (30) calendar days of its receipt of a proposed Research Publication, the Publishing Party agrees to delay its proposed Research Publication for up to thirty (30) additional calendar days to permit the preparation and filing of a patent application(s). The Publishing Party further agrees to delete from its proposed Research Publications any of the Reviewing Party's Confidential Information unless the Reviewing Party agrees in writing to the inclusion of its Confidential Information in those Research Publications.

11. **Press Releases**. The Parties agree to coordinate press releases or other public releases of information related to this Agreement prior to release except that, as necessary to comply with applicable laws, rules, and regulations, or any inquiry of any governmental entity, either Party may release the name of the other Party and a non-confidential general description of the Co-Development Project without prior written approval. Unless agreed otherwise, each Party will use their best efforts to provide any proposed press release related to this Agreement to the other Party for review and comment at least five (5) business days prior to release.

12. **Warranties**. Material and/or Information are provided "as is" without warranty of merchantability or fitness for a particular purpose or any other warranty, express or implied. Provider makes no representations that use of its Material and/or Information will not infringe any patent or other proprietary rights of third parties. Neither Party provides any warranty, express or implied, regarding any matter whatsoever, including without limitation the research conducted under this Agreement or any CRA Invention. EACH PARTY ACKNOWLEDGES THAT MATERIAL IS EXPERIMENTAL AND MAY HAVE UNKNOWN HAZARDOUS CHARACTERISTICS, THAT IT IS AWARE OF THE RISKS OF WORKING WITH EXPERIMENTAL MATERIALS, AND THAT IT WILL STRICTLY ADHERE TO PROPER LABORATORY PROCEDURES FOR HANDLING MATERIALS WITH UNKNOWN HAZARDS. UNLESS APPROVED BY BOTH PARTIES IN ADVANCE BY WRITTEN AGREEMENT, MATERIAL WILL NOT BE USED IN HUMANS.

13. **Indemnification; Procedures**. To the fullest extent permitted by applicable law and except as provided below, each Party shall indemnify, defend and hold harmless the other Party, its employees, officers, directors, governors, managers, subsidiaries, Affiliates, agents and principals (partners, shareholders or holders of an ownership interest, as the case may be) from and against any and all liabilities, losses, damages, costs, fines, fees and/or expenses (including but not limited to reasonable counsel fees, expert fees and court costs) resulting from any claim, action, suit, or proceedings brought by a third-party ("**Third Party Claim**") to the extent resulting from, relating to or arising out of an alleged or actual (a) breach or purported breach by the indemnifying Party of any covenant, representation or warranty set forth in this Agreement; (b) physical injury to persons or damage to property resulting from the gross negligence of the indemnifying Party or its personnel in breach of this Agreement; (c) gross negligence related to the research, development, regulatory approval, or other commercialization of any product or service by, or on behalf of, the other Party or any of its Affiliates; or (d) infringement of patents or other intellectual property rights (including alleged or actual misappropriation of a trade secret) of a third party in connection with the implementation of the Co-Development Project or its method of manufacture of any product of the Co-Development Project, to the extent attributable to the use of the other Party's Background IP, Materials and/or Confidential Information.

    In the event that a Party seeks indemnification pursuant to Section 13, such Party shall: (a) give the other Party prompt written notice of each such Third Party Claim; (b) tender to the other Party control of the defense or settlement of each such Third Party Claim at the other Party's expense and (c) cooperate with the other Party, at the other Party's expense, in defending or settling each such Third Party Claim. Subject to the foregoing, each Party shall have the right to participate at its own expense in any indemnification action or related settlement negotiations using counsel of its own choice. The indemnifying Party shall not settle any Third Party Claim in a manner that adversely affects the rights of the indemnified Party without the indemnified Party's prior written consent, provided, that such consent shall not be unreasonably delayed, conditioned or withheld. The indemnified Party's failure to perform any obligations under this Section 13 shall not relieve the indemnifying Party of its obligations hereunder, except to the extent that the indemnifying Party can demonstrate that it has been prejudiced as a result of such failure.

    For purposes of this Agreement, the below terms have the following meanings:
    "**Affiliate**" means, with respect to a Party, any Person that, directly or indirectly, through one or more intermediaries, controls, is controlled by or under common control with a Party. For the purposes of this definition, "control" (including, with correlative meanings, the terms "controlled by" and "under common control with"), as used with respect to any Person, means (a) ownership, directly or indirectly, of more than fifty percent (50%) of the outstanding voting securities or capital stock (or such lesser percentage which is the maximum allowed to be owned by a foreign corporation in a particular jurisdiction) of such Person, or has other comparable ownership interest with respect to any entity other than a corporation, or (b) the possession, directly or indirectly, of the power to direct or cause the direction of the management or policies of such Person, whether through the ownership of shares, the holding of voting power, by contract or otherwise. For the avoidance of doubt, (i) neither of the Parties, or any of their respective Affiliates, shall be deemed to be an "Affiliate" of such other Party.

    "**Governmental Authority**" means any federal, state, municipal, local, territorial, or other governmental department, regulatory authority, judicial or administrative body, whether in the United States, a foreign country or having international status, including but not limited to the U.S. Food and Drug Administration or equivalent foreign regulatory agencies.

    "**Person**" means an individual, partnership, corporation, limited liability company, association, joint stock company, trust, joint venture, unincorporated organization, Government Entity or department, agency or political subdivision thereof or other entity.

    "**Third Party**" means any other Person other than a Party and their respective Affiliates.

14. **Biosafety; Biosecurity**. Each Party accepts full responsibility for the safety and security of the portion of the Co-Development Project that it conducts, and assures that its portion of the Research Project will be conducted in accordance with all applicable laws, rules, regulations and policies. Where applicable, each Party agrees to abide by all laws, rules, regulations and policies governing biological select agents and toxins.

15. **Animal Welfare.** Each Party agrees that its personnel will conduct its portion of any *in vivo* experiments in accordance with that Party's Institutional Animal Care and Use Committee (IACUC)-approved protocol and in compliance with the Animal Welfare Act, and other applicable national, state and local laws, regulations and policies relating to animals and experiments involving animals.

16. **Export Control**. The obligation of the Parties to transfer technology to one or more other parties, provide technical information and reports to one or more other parties, and otherwise perform under this Agreement are contingent upon compliance with applicable United States export control laws and regulations. The transfer of certain technical data and commodities may require a license from a cognizant agency of the U.S. Government or written assurances by the Parties that the Parties will not export technical data, computer software, or certain commodities to specified foreign countries without prior approval of an appropriate agency of the U.S. Government. The Parties do not, alone or collectively, represent that a license will not be required, nor that, if required, it will be issued. In addition, if applicable, the Parties will comply with all requirements applicable to the shipment of etiologic agents.

17. **Term; Termination**. This Agreement is effective as of February 1, 2023 ("**Effective Date**") for three (3) years. Either Party may terminate this Agreement unilaterally at any time for any reason by giving thirty (30) calendar days' written or email notice to the other Party. For the avoidance of doubt, the early termination or expiration of this Agreement and the licenses and rights granted to each Party hereunder shall not affect any obligation of either Party or its Affiliates may have to pay the other Party in accordance with the terms set forth in Annex B and resulting agreement thereto.

18. **Governing Law**. The construction, validity, performance, and effect of this Agreement will be governed for all purposes by the laws applicable to State of Delaware. Any lawsuit brought to enforce any obligation under this Agreement shall only be brought in the federal or state courts located in State of Delaware. The Parties consent to the personal and exclusive jurisdiction of these courts.

19. **Surviving Provisions**. Paragraphs 2, 3, 4, 5, 9, 10, 11, 13 and 18 to 28 and Annex B survive the expiration or early termination of this Agreement.

20. **Notices.** All notices, demands or other communications to be given or delivered under or by reason of the provisions of this Agreement shall be in writing and shall be deemed to have been given when delivered personally to the recipient, when sent by email upon written confirmation thereof, three (3) business days after being sent to recipient by U.S. First Class mail (postage prepaid), or one (1) business day after being sent to the recipient by reputable overnight courier service (charges prepaid). Such notices, demands and other communications shall be sent to the Parties at the applicable addresses therefore set forth below or to such other address or to the attention of such other person as the recipient party has specified by prior written notice to the sending party. All notices, demands and other communications hereunder may be given by any other means, but shall not be deemed to have been duly given unless and until it is actually received by the intended recipient.

    For AbVacc:

    Mailing Address:
    AbVacc, Inc.
    4 Research Court. Suite 310.
    Rockville, Maryland 20850
    POC for Technical and IP Matters:
    Attn: M. Javad Aman
    Email: jaman@abvacc.com
    POC for Financial matters:
    Attn: Mahtab Hekmat
    Email: mhekmat@abvacc.com

    For BWV:

    Mailing Address:
    Blue Water Vaccines Inc.
    201 E Fifth Street, Suite 1900
    Cincinnati, OH 45202
    POC for Technical and IP Matters:
    Attn: Blair Wigsten
    Email: bwigsten@bluewatervaccines.com
    POC for Financial matters:
    Attn: Erin Henderson
    Email: ehenderson@bluewatervaccines.com

21. **Binding Effect**. The rights and obligations of the Parties under this Agreement shall be binding upon and inure to the benefit of the successors and permitted assigns of the Parties.

22. **Waiver**. Failure by any Party to enforce any term or provision of this Agreement in any specific instance or instances under this Agreement shall not constitute a waiver by such Party of any such term or provision, and such Party may enforce such term or provision in any subsequent instance without any limitation or penalty whatsoever.

23. **Assignment**. Neither this Agreement nor any interest under this Agreement shall be assignable by either Party to any Third Party without the prior written consent of the other Party, not to be unreasonably withheld, delayed or conditioned; except that either Party may assign this Agreement to (i) any of its Affiliates; or (ii) in its entirety in connection with a merger or sale of substantially all of the assets of its business as relating to this Agreement without such consent. Any assignment not in accordance with this Section 23 shall be null and void.

24. **Integration**. This Agreement, which includes each of the Annexes hereto, which are hereby incorporated by this reference, completely and exclusively state the agreement and understanding of the Parties regarding their subject matter. This Agreement supersedes, and its terms govern, all prior proposals, offers, agreements or other communications between the Parties, oral or written, regarding the subject matter herein.

25. **Counterparts**. This Agreement may be executed (including by use of industry standard signature software, such as DocuSign®) in any number of counterparts, each of which shall be deemed to be an original, but all of which shall be deemed to be one agreement. A signature received via facsimile or electronically of a .pdf via e-mail shall be as legally binding for all purposes as an original signature.

26. **Severability**. If any portion of this Agreement is held to be unenforceable, the remainder of this Agreement will remain valid. Further, the term or condition that is held to be illegal or unenforceable shall be modified/reformed by the court to remain in effect as far as possible in accordance with the intention of the Parties.

27. **Interpretation**. The captions and headings to this Agreement are for convenience only, and are to be of no force or effect in construing or interpreting any of the provisions of this Agreement. Unless specified to the contrary, references to Sections or Schedules mean the particular Sections and Schedules to this Agreement and references to this Agreement include all schedules hereto. Unless context otherwise clearly requires, whenever used in this Agreement: (i) the words “include” or “including” shall be construed as incorporating, also, “but not limited to” or “without limitation;” (ii) the word “day” or “year” means a calendar day or year unless otherwise specified; (iii) the word “notice” shall mean notice in writing (whether or not specifically stated); (iv) the words “hereof,” “herein,” “hereby” and derivative or similar words refer to this Agreement (including any Schedules); (v) the word “or” shall be construed as the inclusive meaning identified with the phrase “and/or;”; and (vi) references to any specific law, rule or regulation, or article, section or other division thereof, shall be deemed to include the then-current amendments thereto or any replacement law, rule or regulation thereof.

28. WAIVER OF JURY TRIAL. EACH PARTY HEREBY WAIVES ITS RIGHTS TO A JURY TRIAL OF ANY CLAIM OR CAUSE OF ACTION BASED UPON OR ARISING OUT OF THIS AGREEMENT, THE OTHER TRANSACTION DOCUMENTS OR THE SUBJECT MATTER HEREOF OR THEREOF. THE SCOPE OF THIS WAIVER IS INTENDED TO BE ALL-ENCOMPASSING OF ANY AND ALL DISPUTES THAT MAY BE FILED IN ANY COURT AND THAT RELATE TO THE SUBJECT MATTER OF THE TRANSACTIONS CONTEMPLATED BY THIS AGREEMENT AND THE OTHER TRANSACTION DOCUMENTS, INCLUDING, WITHOUT LIMITATION, CONTRACT CLAIMS, TORT CLAIMS (INCLUDING NEGLIGENCE), BREACH OF DUTY CLAIMS, AND ALL OTHER COMMON LAW AND STATUTORY CLAIMS. THIS SECTION HAS BEEN FULLY DISCUSSED BY EACH OF THE PARTIES HERETO AND THESE PROVISIONS WILL NOT BE SUBJECT TO ANY EXCEPTIONS. EACH PARTY HERETO HEREBY FURTHER WARRANTS AND REPRESENTS THAT SUCH PARTY HAS REVIEWED THIS WAIVER WITH ITS LEGAL COUNSEL, AND THAT SUCH PARTY KNOWINGLY AND VOLUNTARILY WAIVES ITS JURY TRIAL RIGHTS FOLLOWING CONSULTATION WITH LEGAL COUNSEL.

{*Signatures Follow on Next Page*}

IN WITNESS WHEREOF, each Party has caused this Agreement to be executed by its duly authorized representative to be binding and effective as of the Effective Date.

BLUE WATER VACCINES INC.

/s/ Joseph Hernandez
Joseph Hernandez
Chief Executive Officer
Blue Water Vaccines Inc.

February 1, 2023
Date

ABVACC, INC.

/s/ M. Javad Aman
M. Javad Aman
President and Chief Scientific Officer
AbVacc, Inc.

2/1/2023

ANNEX A

Co-Development Project

The initial Co-Development Project will consist of the following vaccine candidates utilizing the Norovirus S and P particle platform:

- Marburg
- Monkeypox
- Malaria

BWV (BWV) will:

- Provide technical expertise, as needed, for the Co-Development project, specifically including:
  - Norovirus platform expertise
  - Monkeypox expertise
  - Malaria expertise
- Provide research material to include:
  - Monkeypox and Vaccinia vaccine material
  - Mouse sera from initial immunogenicity study, if successful.
- Provide sequences for the VLP.
- Support AbVacc for all grant applications, contract writing, etc. needed to successfully submit for non-dilutive funding for program covered by the Agreement.

ABVACC (ABVACC) will:

- Provide technical expertise, as needed, for the Co-Development project, specifically including:
  - Marburg expertise
- Provide grant writing expertise and submit grants on behalf of the Parties.
- Manage grants awarded.

The Parties will:

- use the timeline and activities listed below to conduct the Co-Development Project.
- Discuss the Co-Development Project, Plan and Results and confer regarding any publications or presentations concerning the Co-Development Project. Meetings can be conducted virtually or hosted by either party. The timing and frequency of meetings will be agreed upon by both parties
- Inform each other, in confidence, about any CDA Invention(s), and discuss its/their commercialization potential and strategies for patenting and licensing.
- Use all grant money received for the Co-Development Project, excluding any allowable fees, as outlined in the development plan agreed to by both Parties, and for no other purpose.

Background: Blue Water Vaccines Inc. holds the exclusive development and commercialization rights from Cincinnati Children's Hospital Medical Center for the Norovirus S and P Nanoparticle platform technology. The platform has the potential to provide a vehicle for antigen delivery of multiple infectious diseases. The S particle can present a single antigen. The P particle has the ability to present up to three different antigens. To date, Blue Water Vaccines Inc, along with researchers at Cincinnati Children's and other institutions around the world, have evaluated multiple antigens on both particles. More recently, Blue Water Vaccines began evaluating the S particle as a platform to present a monkeypox antigen with the goal of developing a novel monkeypox vaccine.

Scope

ABVACC and BWV will work collaboratively through the Joint Development Committee to establish and implement a development plan or statement of work for each Co-Development Project targeted product. Initially, the Parties have identified a Marburg vaccine, a Monkeypox vaccine and a malaria vaccine. The Parties agree that additional candidates may be identified for development using the Norovirus S and P particle platform and will be incorporated into this agreement. It is expected that a majority, if not all, of the work conducted from inception to commercialization will be funded through non-dilutive funding.

Goals of the Program

1. Identify and optimize expression system. One of the key challenges for the VLP program is achieving economically viable solubility of the expressed proteins. To date, BWV has identified one potential expression system for the monkeypox vaccine program. Previous analysis on the malaria vaccine candidate was performed at Cincinnati Children's. The original expression system used to produce the malaria vaccine for initial study has not been evaluated for solubility and further analysis is required. A key priority is to determine if a single expression system will be viable for multiple vaccine candidates.

2. Achieve a targeted Technology Readiness Level (TRL) for each product. The Parties will agree on a target TRL, as defined by BARDA, for each identified candidate necessary to receive funding for pivotal clinical trials. ABVACC will lead the grant writing process, relying on the expertise provided by BWV, to develop and submit non-dilutive funding applications that will provide funding to reach the specified TRL for each of the programs.

3. Define achievable path to commercialization. Some of the products targeted for co-development, if not all products, can be defined as medical countermeasures or public health products. As such, each of the programs may have limited market potential. A key focus of the development path will be identifying the most cost-effective approach to commercialization

Annex B
Exclusive Commercialization License Terms

In the event BWV is the primary sponsor of any products under this Agreement, BWV will pay ABVACC the following amounts in immediately available funds within 2 business days after the achievement of any Development Milestone and/or Regulatory Commercial Milestone and on a quarterly basis with respect to any Royalty or Pass Through Payments.

		AbVacc Directed/Antigens	BWV Directed/Antigens
Development Milestones	Filing IND	250K	100K
	Initiation of Phase I Clinical Trial – govt funding	500K	200K
	Initiation of Pivotal Phase 3 Clinical Trial, or Pivotal Animal Studies under FDA Animal Rule – govt funding	1M	300K
Regulatory & Commercial Milestones	First Emergency Use Authorization Sale (Executed on the Sale)	1M	500K
	First FDA approval	1M	500K
	First sale of Product following FDA approval	1M	500K
Royalty	Royalty on net sales	4%	2%
Pass through	If sublicensed pass through on all proceeds from licensee	20%	5%

In the event ABVACC is the primary sponsor of any products under this Agreement, ABVACC will pay BWV the following amounts in immediately available funds within 2 business days after the achievement of any Development Milestone and/or Regulatory Commercial Milestone and on a quarterly basis with respect to any Royalty or Pass Through Payments.

		BWV Directed/Antigens	ABVACC Directed/Antigens
Development Milestones	Filing IND	250K	100K
	Initiation of Phase I Clinical Trial – govt funding	500K	200K
	Initiation of Pivotal Phase 3 Clinical Trial, or Pivotal Animal Studies under FDA Animal Rule – govt funding	1M	300K
Regulatory & Commercial Milestones	First Emergency Use Authorization Sale (Executed on the Sale)	1M	500K
	First FDA approval	1M	500K
	First sale of Product following FDA approval	1M	500K
Royalty	Royalty on net sales	4%	2%
Pass through	If sublicensed pass through on all proceeds from licensee	20%	5%

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, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of Blue Water Biotech, 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(s) 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)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) 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, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

   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;

   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(s) 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 (or persons performing the equivalent functions):

   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 12, 2023

By: /s/ Joseph Hernandez

Joseph Hernandez
Chief Executive Officer
(Principal 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, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of Blue Water Biotech, 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(s) 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)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) 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 is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

   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;

   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(s) 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 (or persons performing the equivalent functions):

   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 12, 2023

By: /s/ Jon Garfield

Jon Garfield
Chief Financial Officer
(Principal Financial Officer)

Exhibit 32.1

CERTIFICATION OF THE
PRINCIPAL EXECUTIVE OFFICER
PURSUANT TO
18 U.S.C. SECTION 1350,
AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Quarterly Report on Form 10-Q of Blue Water Biotech, Inc. (the "Company") for the quarterly period ended March 31, 2023, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Joseph Hernandez, Chief Executive Officer of the Company, certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that to my knowledge:

1. The Report 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 Report fairly presents, in all material respects, the financial condition and results of operations of the Company as of and for the period covered by the Report.

Date: May 12, 2023

By: /s/ Joseph Hernandez
Joseph Hernandez
Chief Executive Officer
(Principal Executive Officer)

Exhibit 32.2

CERTIFICATION OF THE
PRINCIPAL FINANCIAL OFFICER
PURSUANT TO
18 U.S.C. SECTION 1350,
AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Quarterly Report on Form 10-Q of Blue Water Biotech, Inc. (the "Company") for the quarterly period ended March 31, 2023, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Jon Garfield, Chief Financial Officer of the Company, certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that to my knowledge:

1. The Report 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 Report fairly presents, in all material respects, the financial condition and results of operations of the Company as of and for the period covered by the Report.

Date: May 12, 2023

By: /s/ Jon Garfield
Jon Garfield
Chief Financial Officer
(Principal Financial Officer)