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

FORM 10-Q

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

For the quarterly period ended September 30, 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	**83-2262816**
(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

(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 November 17, 2023, the registrant had 18,655,412 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 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 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

	September 30, 2023 (Unaudited)	December 31, 2022
ASSETS		
Current assets		
Cash	$ 7,653,975	$ 25,752,659
Inventories	1,419,272	—
Prepaid expenses and other current assets	467,738	469,232
Receivable from related parties, net	—	35,850
Total current assets	9,540,985	26,257,741
Prepaid expenses, long-term	55,499	38,617
Property and equipment, net	12,503	14,089
Deferred offering costs	366,113	—
Intangible asset	17,906,771	—
Total assets	**$ 27,881,871**	**$ 26,310,447**
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities		
Accounts payable	$ 3,176,332	$ 1,499,296
Accrued expenses	1,538,544	2,409,128
Notes payable, net of debt discount of $569,907	12,920,093	—
Contingent warrant liability	10,461	14,021
Total current liabilities	17,645,430	3,922,445
Commitments and Contingencies (see Note 9)		
Stockholders' equity		
Preferred stock, $0.00001 par value, 10,000,000 shares authorized at September 30, 2023 and December 31, 2022; 10,000 and 0 shares designated as Series A convertible preferred stock at September 30, 2023 and December 31, 2022, respectively; 0 shares issued and outstanding at September 30, 2023 and December 31, 2022	—	—
Common stock, $0.00001 par value, 250,000,000 shares authorized at September 30, 2023 and December 31, 2022; 18,336,597 and 15,724,957 shares issued at September 30, 2023 and December 31, 2022, respectively; 17,819,198 and 15,265,228 shares outstanding at September 30, 2023 and December 31, 2022, respectively	183	157
Additional paid-in-capital	45,297,371	42,331,155
Treasury stock, at cost; 517,399 and 459,729 shares of common stock at September 30, 2023 and December 31, 2022, respectively	(625,791)	(566,810)
Accumulated deficit	(34,435,322)	(19,376,500)
Total stockholders' equity	10,236,441	22,388,002
Total liabilities and stockholders' equity	**$ 27,881,871**	**$ 26,310,447**

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

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

	Three Months Ended September 30, 2023	Three Months Ended September 30, 2022	Nine Months Ended September 30, 2023	Nine Months Ended September 30, 2022
Operating expenses				
Selling, general and administrative	$ 4,268,845	$ 2,694,254	$ 8,337,615	$ 7,311,243
Research and development	219,238	1,175,480	2,148,327	2,924,037
Impairment of deposit on asset purchase agreement	—	—	3,500,000	—
Total operating expenses	4,488,083	3,869,734	13,985,942	10,235,280
Loss from operations	(4,488,083)	(3,869,734)	(13,985,942)	(10,235,280)
Other income (expense)				
Loss on extinguishment of note payable	(490,000)	—	(490,000)	—
Interest expense	(269,097)	—	(483,093)	—
Change in fair value of contingent warrant liability	(99,728)	3,072	(99,787)	33,375
Total other income (expense)	(858,825)	3,072	(1,072,880)	33,375
Net loss	**$ (5,346,908)**	**$ (3,866,662)**	**$ (15,058,822)**	**$ (10,201,905)**
Cumulative preferred stock dividends	—	—	—	96,359
Net loss applicable to common stockholders	$ (5,346,908)	$ (3,866,662)	$ (15,058,822)	$ (10,298,264)
Net loss per share attributable to common stockholders, basic and diluted	$ (0.31)	$ (0.27)	$ (0.92)	$ (0.94)
Weighted average number of common shares outstanding, basic and diluted	17,521,562	14,338,379	16,452,136	10,949,265

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

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

	Preferred Stock		Common Stock		Additional Paid-in	Treasury Stock		Accumulated	Total Stockholders'
	Shares	Amount	Shares	Amount	Capital	Shares	Amount	Deficit	Equity
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**
Exercise of stock options	—	—	45,920	—	459	—	—	—	459
Issuance of restricted stock	—	—	512,940	5	(5)	—	—	—	—
Stock-based compensation	—	—	—	—	272,781	—	—	—	272,781
Purchase of treasury shares	—	—	—	—	—	(25,032)	(25,527)	—	(25,527)
Net loss	—	—	—	—	—	—	—	(6,865,270)	(6,865,270)
Balance at June 30, 2023	—	$ —	**16,930,457**	**$ 169**	**$42,789,961**	**(517,399)**	**$(625,791)**	**$ (29,088,414)**	**$ 13,075,925**
Issuance of common stock from exercise of preferred investment options	—	—	1,575,000	16	2,272,822	—	—	—	2,272,838
Issuance of warrants for settlement of contingent warrants	—	—	—	—	129,184	—	—	—	129,184
Stock-based compensation	—	—	—	—	105,402	—	—	—	105,402
Restricted stock forfeitures	—	—	(168,860)	(2)	2	—	—	—	—
Net loss	—	—	—	—	—	—	—	(5,346,908)	(5,346,908)
Balance at September 30, 2023	—	$ —	**18,336,597**	**$ 183**	**$45,297,371**	**(517,399)**	**$(625,791)**	**$ (34,435,322)**	**$ 10,236,441**

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

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

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

	Nine Months Ended September 30, 2023	Nine Months Ended September 30, 2022
Cash flows from operating activities		
Net loss	$ (15,058,822)	$ (10,201,905)
Adjustments to reconcile net loss to net cash used in operating activities:		
Impairment of deposit on asset purchase agreement	3,500,000	—
Stock-based compensation	563,761	1,796,268
Amortization of debt discount	483,093	—
Loss on extinguishment of note payable	490,000	—
Loss on impairment of other long-lived assets	267,019	—
Loss on related party receivable	265,648	—
Depreciation expense	4,886	4,906
Change in fair value of contingent warrant liability	99,787	(33,375)
Changes in assets and liabilities:		
Inventories	(299,272)	—
Prepaid expenses and other current assets	(9,526)	(469,278)
Prepaid expenses, long-term	(16,882)	(66,357)
Deposit	—	(27,588)
Accounts payable	1,418,048	361,103
Accrued expenses	(976,871)	2,760,734
Net cash used in operating activities	(9,269,131)	(5,875,492)
Cash flows from investing activities		
Acquisition of assets, including transaction costs of $79,771	(6,079,771)	—
Deposit made in connection with asset purchase agreement	(3,500,000)	—
Purchases of other long-lived assets	(51,744)	—
Net advances to related parties	(229,798)	(22,149)
Purchases of property and equipment	(3,300)	(9,339)
Net cash used in investing activities	(9,864,613)	(31,488)
Cash flows from financing activities		
Purchase of treasury shares	(58,981)	—
Payment of deferred offering costs	(205,093)	(51,304)
Principal payment of note payable	(1,000,000)	—
Proceeds from exercise of preferred investment options, net	2,298,675	—
Proceeds from exercise of stock options	459	1,655
Proceeds from issuance of common stock in initial public offering, net of underwriting discount	—	18,400,000
Payments of initial public offering costs	—	(926,972)
Proceeds from issuance of common stock and warrants in private placements, net of placement agent discount	—	16,468,123
Payment of private placement issuance costs		(777,225)
Proceeds from exercise of pre-funded warrants	—	945
Net cash provided by financing activities	1,035,060	33,115,222
Net increase (decrease) in cash	(18,098,684)	27,208,242
Cash, beginning of period	25,752,659	1,928,474
Cash, end of period	$ 7,653,975	$ 29,136,716
Noncash investing and financing activities:		
Inventory and intangible assets acquired through issuance of notes payable	$ 12,947,000	$ —
Incremental fair value of exchanged preferred investment options	$ 2,613,011	$ 860,204
Deferred offering costs included in accounts payable and accrued expenses	$ 150,000	$ 125,000
Recognition of contingent warrant liability	$ 25,837	$ 75,431
Warrants issued for settlement of contingent warrants	$ 129,184	$ —
Deferred offering costs previously included in prepaid expenses	$ (11,020)	$ —
Exercise of pre-funded warrants	$ 7	$ 6
Issuance of restricted stock	$ 5	$ —
Restricted stock forfeitures	$ (2)	$ —
Payment of accrued bonus through related party receivable	$ —	$ 140,000
Private placement offering costs included in accounts payable	$ —	$ 67,823
Conversion of convertible preferred stock to common stock upon initial public offering	$ —	$ 45

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

BLUE WATER BIOTECH, INC.
Notes to Condensed Financial Statements
September 30, 2023
(Unaudited)

Note 1 — Organization and Basis of Presentation

Organization and Nature of Operations

Blue Water Biotech, Inc. (formerly known as Blue Water Vaccines Inc.) (the "Company") was formed on October 26, 2018. Historically, the Company's focus was on the research and development of transformational vaccines to prevent infectious diseases worldwide. In April 2023, the Company acquired ENTADFI®, with plans to commercialize it. ENTADFI® is a Food and Drug Administration ("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. During the third quarter of 2023, the Company deprioritized its efforts on vaccine development activities to pursue and focus on commercialization activities for ENTADFI®. On October 30, 2023, the Company announced a new business strategy of focusing its efforts on building a foundation of therapeutic, diagnostic, and service products in the field of oncology that will bolster and enrich the practice of medicine for clinicians. ENTADFI® will become the inaugural therapeutic drug in the Company's expanding portfolio of oncology therapeutics once launched.

On April 21, 2023, the Company filed an amendment to its Articles of Incorporation 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 31, 2023, the board of directors of the Company (the "Board") amended the Company's bylaws to reduce the quorum requirement at meetings of the Company's stockholders from a majority of the voting power of the outstanding shares of stock of the Company entitled to vote, to one-third of the voting power of the outstanding shares of stock of the Company entitled to vote, effective immediately. No other changes were made to the bylaws.

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 September 30, 2023, and the condensed statements of operations and the condensed statements of changes in stockholders' equity for the three and nine months ended September 30, 2023 and 2022, and the condensed statements of cash flows for the nine months ended September 30, 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 September 30, 2023 and its results of operations for the three and nine months ended September 30, 2023 and 2022, and its cash flows for the nine months ended September 30, 2023 and 2022. The financial data and the other financial information disclosed in the notes to these condensed financial statements related to the three and nine-month periods are also unaudited. Operating results for the three and nine months ended September 30, 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, engaging in research and development activities, and potential asset and business acquisitions. 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 8). 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. During the three and nine months ended September 30, 2023, the Company received net proceeds of approximately $2.3 million in connection with the exercise of preferred investment options by an investor (see Note 8).

The Company has incurred substantial operating losses since inception and expects to continue to incur significant operating losses for the foreseeable future. As of September 30, 2023, the Company had cash of approximately $7.7 million, a working capital deficit of approximately $8.1 million and an accumulated deficit of approximately $34.4 million.

During June 2023, the Company entered into an asset purchase agreement with WraSer (the "WraSer APA") for the acquisition of a significant portion of other assets that requires the Company to pay consideration of $8.5 million and one million shares of common stock, of which $3.5 million was paid upon execution of the agreement, $4.5 million of the remainder and common stock was to be paid at closing, and the remaining $500,000 was to be due June 13, 2024. On September 26, 2023, WraSer and its affiliates filed for relief under chapter 11 of the U.S. Bankruptcy Code in the Bankruptcy Court. On October 4, 2023, the parties agreed to amend the WraSer APA. The amendment, which is subject to court approval, seeks, among other things, to eliminate the $500,000 post-closing payment due June 13, 2024 and stagger the $4.5 million cash payment that the Company would otherwise have to pay at closing to: (i) $2.2 million to be paid at closing, (ii) $2.3 million, to be paid in monthly installments of $150,000 commencing January 2024 and (iii) 789 shares of Series A Preferred Stock to be paid at closing. On October 6, 2023, the Company was alerted to certain developments in WraSer's operations relating to WraSer's inability to manufacture the active pharmaceutical ingredient for one of the key WraSer Assets, which development the Company believes constitutes a Material Adverse Effect (as such term is defined in the WraSer APA) that will prevent the Company from closing the transaction. On October 20, 2023, the Company filed a motion for relief from the automatic stay in the Bankruptcy Court so that the Company can exercise the termination rights under the WraSer APA, as amended. WraSer has advised the Company that it does not believe that a Material Adverse Event occurred. If the Bankruptcy Court does not grant the Company's motion and requires it to complete the transaction, the Company will not be able to execute its commercialization strategy for the WraSer Assets because there is no manufacturer for the active pharmaceutical ingredient for Zontivity, the key driver for the WraSer acquisition. Due to the WraSer bankruptcy filing and the Company's status as an unsecured creditor of WraSer, it is also unlikely that the Company will recover the $3.5 million initial payment made or any costs and resources in connection with services provided by the Company under the WraSer Management Services Agreement. In addition, if the WraSer APA is terminated, the Company will not be able to recover any such costs.

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 in the short-term to fund its continuing operations, satisfy existing and future obligations and liabilities, including the remaining payments due for the acquisition of assets described in Note 5 and other contracts entered into in support of the Company's commercialization plans, in addition to funds needed to support the Company's working capital needs and business activities. These business activities include the commercialization of ENTADFI®, and the development and commercialization of the Company's current product candidates and future product candidates. Management's plans include generating product revenue from sales of ENTADFI®, which has not yet been successfully commercialized, a process that will require significant amounts of additional capital to complete. In addition, certain of the commercialization activities 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, and obtaining required licensure in various jurisdictions, 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, which creates significant uncertainty that the Company will be able to successfully launch ENTADFI®. If the Company is unable to secure additional capital, it may be required to defer any future clinical trials, should the Company decide to resume these activities, 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 nine months ended September 30, 2023, there were changes to the Company's significant accounting policies described in the Company's Annual Report on Form 10-K for the year ended December 31, 2022, as follows:

Use of Estimates

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

Segment Information

Operating segments are defined as components of an enterprise about which separate discrete information is available for evaluation by the chief operating decision maker ("CODM"), or decision-making group, in deciding how to allocate resources and in assessing performance. Prior to the acquisition of ENTADFI® during the quarter ended June 30, 2023, the Company managed one distinct business segment, which was vaccine discovery and development. During the second quarter of 2023, as a result of the acquisition of ENTADFI® for which the Company is working towards commercial launch, the Company operated in two business segments: research and development and commercial. During the third quarter of 2023, the Company deprioritized its vaccine discovery and development programs, and accordingly, as of September 30, 2023, the Company was operating in one segment: commercial. Management's determination that the Company operated as two segments during the second quarter of 2023 and one segment during the third quarter of 2023, was consistent with the financial information regularly reviewed by the CODM for purposes of evaluating performance, allocating resources, setting incentive compensation targets, and planning and forecasting for future periods.

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

Inventories

Inventories consist of raw materials, packaging materials, and work-in-process. Inventories are stated at the lower of cost or net realizable value, with cost determined on a first-in, first-out basis, aside from inventory acquired in an asset acquisition, which is recorded at fair value. The Company periodically reviews the composition of inventory in order to identify excess, obsolete, slow-moving or otherwise non-saleable items taking into account anticipated future sales compared with quantities on hand, and the remaining shelf life of goods on hand. If non-saleable items are observed and there are no alternate uses for the inventory, the Company records a write-down to net realizable value in the period that the decline in value is first recognized. The Company had no inventory reserves at September 30, 2023 and December 31, 2022.

Acquisitions

The Company evaluates acquisitions to first determine whether a set of assets acquired constitutes a business and should be accounted for as a business combination. If the assets acquired are not a business, the transaction is accounted as an asset acquisition in accordance with Accounting Standards Codification ("ASC") 805-50, *Asset Acquisitions* ("ASC 805-50"), which requires the acquiring entity to recognize assets acquired and liabilities assumed based on the cost to the acquiring entity on a relative fair value basis, except for non-qualifying assets including financial assets such as inventory. Further, the cost of the acquisition includes the fair value of consideration transferred and direct transaction costs attributable to the acquisition. Goodwill is not recognized in an asset acquisition and any excess consideration transferred over the fair value of the net assets acquired is allocated to the identifiable assets based on relative fair values. Contingent consideration payments in asset acquisitions are recognized when the contingency is determined to be probable and reasonably estimable. If the assets acquired are a business, the Company accounts for the transaction as a business combination. Business combinations are accounted for by using the acquisition method of accounting. Under the acquisition method, assets acquired, and liabilities assumed are recorded at their respective fair values. The excess of the fair value of consideration transferred over the fair value of the net assets acquired is recorded as goodwill. Contingent consideration obligations are recorded at their fair values on the acquisition date and remeasured at their fair values each subsequent reporting period until the related contingencies are resolved. The resulting changes in fair values are recorded in earnings.

Intangible Assets

Intangible assets are reported at cost, less accumulated amortization. Intangible assets with finite lives are amortized over their estimated useful lives, starting when sales for the related product begin. Amortization is calculated using the straight-line method.

During the ordinary course of business, the Company has entered into certain license and asset purchase agreements. Potential milestone payments for development, regulatory, and commercial milestones are recorded when the milestone is probable of achievement. Upon a milestone being achieved, the associated milestone payment is capitalized and amortized over the remaining useful life for approved products, or expensed as research and development expense for milestones relating to products whose FDA approval has not yet been obtained.

Impairment of Long-Lived Assets

The Company reviews long-lived assets, including intangible assets with finite useful lives, for impairment whenever events or changes in business circumstances indicate that the carrying amount of the assets may not be fully recoverable (a "triggering event"). Factors that the Company considers in deciding when to perform an impairment review include significant underperformance of the long-lived asset in relation to expectations, significant negative industry or economic trends, and significant changes or planned changes in the use of the assets. If an impairment review is performed to evaluate a long-lived asset for recoverability, the Company compares forecasts of undiscounted cash flows expected to result from the use and eventual disposition of the long-lived asset to its carrying value. An impairment loss would be recognized when estimated undiscounted future cash flows expected to result from the use of an asset are less than its carrying amount. The impairment loss would be based on the excess of the carrying value of the impaired asset over its fair value, determined based on discounted cash flows. During the three and nine months ended September 30, 2023, the Company recorded an impairment loss of approximately $267,000 related to $267,000 of implementation costs incurred under cloud computing hosting arrangements that were capitalized during the three and nine months ended September 30, 2023. There were no other impairment losses on long-lived assets.

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

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

Inventories

Inventories relate to ENTADFI® product and consisted of the following as of September 30, 2023, and December 31, 2022:

	September 30, 2023	December 31, 2022
Raw materials	$ 329,780	$ -
Work-in-process	1,089,492	-
Total	**$ 1,419,272**	**$ -**

Prepaid Expenses and Other Current Assets

Prepaid expenses and other current assets consisted of the following as of September 30, 2023, and December 31, 2022:

	September 30, 2023	December 31, 2022
Prepaid insurance	$ 277,058	$ 148,789
Prepaid research and development	89,195	231,981
Prepaid other	101,485	88,462
Total	**$ 467,738**	**$ 469,232**

Accrued Expenses

Accrued expenses consisted of the following as of September 30, 2023, and December 31, 2022:

	September 30, 2023	December 31, 2022
Accrued research and development	$ 548,287	$ 847,747
Accrued compensation	386,087	1,132,859
Accrued deferred offering costs	125,000	125,000
Accrued professional fees	216,000	—
Accrued implementation fees	106,287	—
Other accrued expenses	156,883	125,922
Accrued franchise taxes	—	177,600
Total	**$ 1,538,544**	**$ 2,409,128**

Note 5 — Acquisitions

ENTADFI®

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

In accordance with the ENTADFI® APA, the Company agreed to provide Veru with initial consideration totaling $20.0 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 ENTADFI® APA require the Company to pay Veru 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.

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 Veru 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, payable to Camargo as follows: (i) $5.0 million is payable upon the first time the Company achieves net sales from ENTADFI® of $100.0 million during a calendar year, (ii) $7.5 million is payable upon the first time the Company achieves net sales from ENTADFI® of $200.0 million during a calendar year, and (3) $10.0 million is payable upon the first time the Company achieves net sales from ENTADFI® of $300.0 million during a calendar year.

On September 29, 2023, the Company entered into an amendment to the ENTADFI® APA (the "ENTADFI® APA Amendment"), which provides that the $4.0 million note payable originally due on September 30, 2023, was deemed paid and fully satisfied upon (1) the payment to the Seller of $1.0 million in cash on September 29, 2023, and (2) the issuance to the Seller by October 3, 2023 of 3,000 shares of Series A Convertible Preferred Stock (the "Series A Preferred Stock") of the Company (see Note 8). Pursuant to the ENTADFI®APA Amendment, the Series A Preferred Stock will convert to common stock of the Company one year from the date of issuance, if the required stockholder approval is obtained. The Series A Preferred Stock, which was issued to the Seller subsequent to September 30, 2023, is initially convertible, in the aggregate, into 5,709,935 shares of the Company's common stock, subject to adjustment and certain shareholder approval limitations specified in the Certificate of Designations. Pursuant to the ENTADFI® APA Amendment, the Company agreed to use commercially reasonable efforts to obtain such shareholder approval by December 31, 2023. The Company also agreed to include the shares of common stock issuable upon conversion of the Series A Preferred Stock in the next resale registration statement filed with the SEC.

Also, in connection with the Transaction, and pursuant to the ENTADFI® APA, the Company entered into non-competition and non-solicitation agreements (the "Non-Competition Agreements") with two of Veru'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 ENTADFI® APA) for a period of five years from the closing of the Transaction.

The acquisition of ENTADFI® has been accounted for as an asset acquisition in accordance with ASC 805-50 because substantially all of the fair value of the assets acquired is concentrated in a single asset, the ENTADFI® product rights. The ENTADFI® products rights consist of trademarks, regulatory approvals, and other records, and are considered a single asset as they are inextricably linked.

Note 5 — Acquisitions (cont.)

The following table summarizes the aggregate consideration transferred for the assets acquired by the Company in connection with the ENTADFI® APA:

	Consideration Transferred
Consideration transferred at closing	$ 6,000,000
Fair value of notes payable issued	12,947,000
Transaction costs	79,771
Total consideration transferred	**$ 19,026,771**

The fair value of the non-interest bearing notes payable was estimated using a net present value model using discount rates averaging 8.2%. The resulting fair value is being accreted to the face value of the notes, through the respective maturity dates. Management evaluated the Milestone Payments and determined that at the close of the Transaction, they are not considered probable, and as such, the Company did not recognize any amount related to the Milestone Payments in the consideration transferred.

The following table summarizes the assets acquired with the ENTADFI® APA:

	Assets Recognized
Inventory	$ 1,120,000
ENTADFI® Intangible	17,906,771
Total fair value of identifiable assets acquired	**$ 19,026,771**

In accordance with ASC 805-50, the acquired inventory was recorded at fair value. The remaining consideration transferred was allocated to the ENTADFI® intangible asset, which will be amortized over its estimated useful life, starting when ENTADFI® sales begin. The Company originally estimated the useful life to be five years, but during the three months ended September 30, 2023, the useful life was reevaluated and changed to seven years. This change in estimate has no accounting impact as the amortization period has not yet begun. Acquired inventory is comprised of work-in-process and raw materials. The fair value of work-in-process inventory was determined based on an estimated sales price of the finished goods, adjusted for costs to complete the manufacturing process, costs of the selling effort, a reasonable profit allowance for the remaining manufacturing and selling effort, and an estimate of holding costs. The fair value of raw materials was determined to approximate replacement cost. The inventory fair value adjustment was approximately $0.3 million and will be amortized as inventory turns over, which is expected to approximate 1.5 years.

Management evaluated the Camargo Obligations and determined that at the close of the Transaction, the related sales milestone payments are not considered probable, and as such, the Company did not recognize any related liability at the date of the Transaction. In addition, royalties under the Camargo Obligations will be recorded as cost of sales, as the related sales are generated and recognized.

WraSer:

On June 13, 2023 (the “Execution Date”), the Company entered into an asset purchase agreement with WraSer, LLC, and affiliates (the “Seller”) (the “WraSer APA”). Pursuant to, and subject to the terms and conditions of, the WraSer APA, on the Closing Date (as defined below) the Company was to purchase six FDA-approved pharmaceutical assets across several indications, including cardiology, otic infections, and pain management (the “WraSer Assets”).

Under the terms of the WraSer APA, the Company was to purchase the WraSer Assets for (i) $3.5 million in cash at signing of the WraSer APA; (ii) $4.5 million in cash on the later of (x) 90 days after the signing of the WraSer APA or (y) the date that all closing conditions under the WraSer APA are met or otherwise waived (the “Closing Date”); (iii) 1.0 million shares of the Company’s common stock (the “Closing Shares”) issuable on the Closing Date, and (iv) $500,000 in cash one year from the Closing Date. On October 4, 2023, the Company and WraSer agreed to amend the WraSer APA (“WraSer APA Amendment”), to modify the payment terms of the transaction, which amendment is currently pending court approval (see Note 14).

Note 5 — Acquisitions (cont.)

Within 90 days of the Closing Date, the Company will use its best efforts to file with the SEC, (at its sole cost and expense,) a registration statement to register, on Form S-3 registering under the Securities Act of 1933, as amended (the "Securities Act"), the resale of the Closing Shares and will use its best efforts to have the registration statement declared effective as soon as practicable after filing.

In conjunction with the WraSer APA, the Company and the Seller entered into a Management Services Agreement (the "MSA") on the Execution Date. Pursuant to the terms of the MSA, the Company will act as the manager of the Seller's business during the period between the Execution Date and Closing Date. During this period, the Company will make advances to WraSer, if needed. If, on the Closing Date, the Seller's cash balance is in excess of the target amount ("Cash Target") specified in the MSA, the Company will apply that excess to the $4.5 million cash payment due upon closing. Conversely, if there is a shortfall, the Company will be required to remit the difference to the Seller over time.

The WraSer APA can be terminated prior to closing as follows (i) upon agreement with all parties; (ii) upon breach of contract of either party, uncured within 20 days of notice. If the WraSer APA is terminated upon agreement with all parties or upon uncured breach of contract by the Company, the initial $3.5 million payment is retained by the Sellers. If it is determined that there is an uncured breach of contract by the Seller, and the WraSer APA is terminated, the Company will have an unsecured claim against WraSer for the $3.5 million payment made by the Company upon execution of the WraSer APA. The closing of the transaction is subject to certain customary closing conditions, including submission of the FDA transfer documentation to transfer ownership of the acquired product regulatory approvals to the Company.

Management evaluated the terms of the WraSer APA and MSA, and determined that, at the Execution Date, control under the provisions of ASC 805, *Business Combinations*, did not transfer to the Company; if the transaction closes, control will transfer then, and the acquisition date will be the closing date. Management further evaluated the requirements pursuant to ASC 810, *Consolidations*, and determined based on the terms of the MSA, and the Company's involvement in the Seller's business, that the Seller is a variable interest entity ("VIE") to the Company. Management determined that the Company is not the primary beneficiary of the VIE as the WraSer APA and MSA do not provide the Company with the power to direct the activities of the VIE that most significantly impact the VIE's economic performance. While the Company was involved in the day-to-day business activities of the VIE until WraSer filed for relief under Chapter 11 of the U.S. Bankruptcy Court (see below), the Seller had to approve substantially all business activities and transactions that significantly impact the economic performance of WraSer during the term of the MSA. Additionally, the Company is not required to absorb the losses of WraSer if the WraSer APA does not close. As such, the Company is not required to consolidate WraSer in the Company's financial statements as of September 30, 2023. The Company recorded the initial $3.5 million payment as a deposit. The Company does not have any liabilities recorded as of September 30, 2023 associated with its variable interest in the Seller, and its exposure to the Seller's losses is limited to no more than the shortfall, if any, of the Cash Target amount of approximately $1.1 million compared to the Seller's cash balance on the Closing Date.

On September 26, 2023, WraSer and its affiliates filed for relief under chapter 11 of the U.S. Bankruptcy Code in the United States Bankruptcy Court for the Middle District of Florida (the "Bankruptcy Court"), and on October 6, 2023, the Company was alerted to certain issues in WraSer's operations that the Company believes constitutes a Material Adverse Effect (as such term is defined in the WraSer APA) that will prevent the Company from closing the transaction. On October 20, 2023, the Company filed a motion for relief from the automatic stay in the Bankruptcy Court so that the Company can exercise the termination rights under the WraSer APA, as amended. WraSer has advised the Company that it does not believe that a Material Adverse Event occurred. If the Bankruptcy Court does not grant the Company's motion and requires it to complete the transaction, the Company will not be able to execute its commercialization strategy for the WraSer Assets because there is no manufacturer for the active pharmaceutical ingredient for Zontivity, the key driver for the WraSer acquisition. Due to the Company's status as an unsecured creditor of WraSer, it is unlikely that the Company will recover the $3.5 million initial payment made or any costs and resources in connection with services provided by the Company under the WraSer MSA and therefore the deposit recorded is impaired. Management determined that the conditions resulting in impairment existed at September 30, 2023, and accordingly, the Company recorded a loss on impairment for the $3.5 million deposit during the nine months ended September 30, 2023.

Note 6 — 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. See Note 9. The OUI Agreement will expire upon ten (10) years from the expiration of the last patent contained in the licensed patent rights, unless terminated earlier. During the year ended December 31, 2021, the U.S. Patent related to immunogenic composition was issued to OUI. This patent expires in August 2037. No additional patents have been issued during the three and nine months ended September 30, 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. Subsequent to September 30, 2023, the Company terminated the license agreement with Oxford University Innovation (see Note 14). The amounts due upon termination of the license agreement were not significant.

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. See Note 9. 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. Subsequent to September 30, 2023, the Company terminated the license agreement with St. Jude (see Note 14). The amounts due upon termination of the license agreement were not significant.

Note 6 — Significant Agreements (cont.)

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. See Note 9. 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.

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, current good manufacturing practice ("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 and nine months ended September 30, 2023, the Company incurred related research and development expense (net gain) of approximately ($56,000) and $231,000, respectively, and at September 30, 2023, the Company had approximately $900,000 recorded as related accounts payable and accrued expenses. During the three and nine months ended September 30, 2022, the Company incurred related research and development expenses of approximately $496,000 and $988,000, respectively.

Note 6 — Significant Agreements (cont.)

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 and nine months ended September 30, 2023, the Company incurred approximately $2,000 and $21,000, respectively, in costs for research and development related to the Co-Development Agreement. As of September 30, 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 September 30, 2023.

Services Agreement

On July 21, 2023, the Company, entered into a Licensing and Services Master Agreement ("Master Services Agreement") and a related statement of work with a vendor, pursuant to which the vendor will provide to the Company commercialization services for the Company's products, including recruiting, managing, supervising and evaluating sales personnel and providing sales-related services for such products, for fees totaling up to $29.1 million over the term of the statement of work. The statement of work had a term through September 6, 2026, unless earlier terminated in accordance with the Master Services Agreement and the statement of work. On July 29, 2023, a second statement of work was entered into with the same vendor for certain subscription services providing prescription market data access to the Company. The fees under this statement of work totaled approximately $800,000, and the term was through July 14, 2025. As of September 30, 2023, the Company prepaid approximately $865,000 for commercialization services under the first statement of work. The Company also had approximately $898,000 recorded in related accounts payable as of September 30, 2023. As the prepayment can be applied against amounts invoiced from the vendor, the prepayment of approximately $865,000 has been offset against accounts payable in the accompanying condensed balance sheet. On October 12, 2023, the Company terminated the Master Services Agreement and statements of work (see Note 14).

Note 7 — Notes Payable

In connection with the ENTADFI® APA (see Note 5), the Company executed three non-interest bearing notes payable (the "Notes") in the principal amounts of $4.0 million, $5.0 million and $5.0 million with maturity dates of September 30, 2023, April 19, 2024, and September 30, 2024, respectively. No principal payments are due until maturity; however, the Company may voluntarily prepay the Notes with no penalty. Additionally, in an Event of Default, as defined in the Notes, the unpaid principal amount of the Notes will accrue interest at a rate of 10.0% per annum.

On September 29, 2023, the Company and the note holder entered into an amendment to the ENTADFI® APA, which provided that the $4.0 million note payable originally due on September 30, 2023, was deemed paid and fully satisfied upon (1) the payment to the Seller of $1.0 million in cash on September 29, 2023, and (2) the issuance to the Seller by October 3, 2023 of 3,000 shares of Series A Preferred Stock of the Company (see Notes 5 and 14). In connection with the ENTADFI® APA Amendment, the Company recorded an extinguishment loss on the note payable of approximately $490,000, which represents the difference between the fair value of the Series A Preferred Stock that will be issued to settle the debt and the carrying value of the note payable as of September 29, 2023. The balance of the note payable included in the accompanying condensed balance sheet at September 30, 2023, has been adjusted to the fair value of the Series A Preferred Stock that was issued and relieved the obligation on October 3, 2023. The extinguishment loss is recognized in other income (expense) in the accompanying condensed statements of operations for the three and nine months ended September 30, 2023.

To determine the fair value of the Series A Preferred Stock, the Company first derived the business enterprise value ("BEV") using a discounted cash flow method. The BEV was adjusted to an equity value assuming $3.0 million of debt converted to Series A Preferred Stock, which was then allocated across the Company's securities. The concluded value for the Series A Preferred Stock utilized the Black-Scholes option pricing model, which was classified as level 3 in the valuation hierarchy due to the presence of significant unobservable inputs. The following key assumptions were used in the model: volatility rate of 100%, risk free interest rate of 4.6%, 5.0 year expected term, and the Company's aggregate equity value. The volatility was based on the historical and implied volatility of a peer group and the risk-free interest rate was based on the implied yield available on U.S. Treasury securities with a term commensurate with the estimated expected term.

The Company imputed interest on the Notes using an average discount rate of 8.2% and recorded a debt discount of approximately $1.1 million at the issuance date. The debt discount is reflected as a reduction in the carrying amount of the Notes and amortized to interest expense through the respective maturity dates, using the effective interest method. The Company recorded approximately $0.3 million and $0.5 million of associated interest expense during the three and nine months ended September 30, 2023, respectively. The unamortized debt discount as of September 30, 2023 was approximately $0.6 million.

Future minimum principal payments on the Notes as of September 30, 2023 includes $3.0 million in principal that was settled through issuance of Series A Preferred Stock in October 2023 and $10 million in principal payments that are due in 2024.

Note 8 — 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.

Preferred Stock

On September 29, 2023, the Company filed a Certificate of Designations of Rights and Preferences of Series A Convertible Preferred Stock of the Company (the "Certificate of Designations") with the State of Delaware to designate and authorize the issuance of up to 10,000 shares of Series A Preferred Stock. Pursuant to the Certificate of Designations, each share of Series A Preferred Stock is convertible into that number of shares of the Company's common stock determined by dividing the Stated Value (as defined in the Certificate of Designations) of $1,000 per share by the Conversion Price (as defined in the Certificate of Designations) of $0.5254 per share, subject to adjustment as provided in the Certificate of Designations, subject to certain shareholder approval limitations. The Series A Preferred Stock is entitled to share ratably in any dividends paid on the Company's common stock (on an as-if-converted-to-common-stock basis), has no voting rights except as to certain significant matters specified in the Certificate of Designations, and has a liquidation preference equal to the Stated Value of $1,000 per share plus any accrued but unpaid dividends thereon. The Series A Preferred Stock is redeemable in whole or in part at the Company's option at any time. The Certificate of Designations authorized the issuance of up to 10,000 shares of Series A Preferred Stock. As of September 30, 2023, there were no shares of Series A Convertible Preferred Stock outstanding (see Notes 5 and 14).

Note 8 — Stockholders' Equity (cont.)

Common Stock

As of September 30, 2023, and December 31, 2022, there were 18,336,597 and 15,724,957 shares of common stock issued, respectively, and 17,819,198 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 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 nine months ended September 30, 2023, the Company repurchased 57,670 shares of common stock, for an aggregate of approximately $59,000, at an average price of $1.02 per share. There were no repurchases of common stock during the three months ended September 30, 2023. 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 September 30, 2023, there are approximately 4.5 million shares remaining, that can be repurchased under the Repurchase Program.

Private Investments in Public Equity

April 2022 Private Placement

On April 19, 2022, the Company consummated the closing of a private placement (the "April 2022 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 2022 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 2022 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 2022 Private Placement, as discussed below.

H.C. Wainwright & Co., LLC ("Wainwright") acted as the exclusive placement agent for the April 2022 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 2022 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 2022 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 of 70,849 were exchanged in connection with the August 2022 Private Placement, as discussed below.

Note 8 — Stockholders' Equity (cont.)

The Company evaluated the terms of the April 2022 Private Placement Warrants and determined that they should be classified as equity instruments based upon accounting guidance provided in ASC 480, *Distinguishing Liabilities from Equity* ("ASC 480") and ASC 815-40, *Derivatives and Hedging – Contracts in Entity's Own Equity* ("ASC 815-40"). Since the Company determined that the April 2022 Private Placement Warrants were equity-classified, the Company recorded the proceeds from the April 2022 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 (expense) in the accompanying condensed statements of operations.

August 2022 Private Placement

On August 11, 2022, the Company consummated the closing of a private placement (the "August 2022 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 2022 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 2022 Private Placement were approximately $8.7 million, after deducting placement agent fees and other offering expenses. In addition, the investors in the August 2022 Private Placement, who are the same investors from the April 2022 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 nine months ended September 30, 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. During the three and nine months ended September 30, 2023, 2,486,214 of these preferred investment options were exercised at a reduced exercise price of $1.09, in connection with the warrant inducement transaction discussed below. As of September 30, 2023, 2,486,214 preferred investment options are outstanding.

Wainwright acted as the exclusive placement agent for the August 2022 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 2022 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 2022 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 2022 Private Placement.

The Company evaluated the terms of the August 2022 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 2022 Private Placement Warrants were equity-classified, the Company recorded the proceeds from the August 2022 Private Placement, net of issuance costs, within common stock at par value and the balance of the net proceeds to additional paid in capital.

Note 8 — Stockholders' Equity (cont.)

The investors in the April 2022 Private Placement agreed to cancel the aggregate of 1,180,812 preferred investment options issued in the April 2022 Private Placement, as part of their participation in the August 2022 Private Placement. The preferred investment options that were cancelled were effectively exchanged for 1,289,148 new preferred investment options in the August 2022 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 2022 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 condensed statements of operations. The remaining 227,497 August Contingent Warrants were measured as a liability upon the close of the August 2022 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.

During the three and nine months ended September 30, 2023, in connection with the warrant inducement transaction, the Company issued to Wainwright as settlement of the contingent warrant liability associated with 149,173 of the August Contingent Warrants, which was triggered upon exercise of the underlying preferred investment options. See *Warrant Inducement* below for further discussion.

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. 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.

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 September 30, 2023, no shares have been sold under the ATM Offering.

Warrant Inducement

On July 31, 2023, the Company entered into a common stock preferred investment options exercise inducement offer letter (the "Inducement Letter") with a certain holder (the "Holder") of existing preferred investment options ("PIOs") to purchase shares of the Company's common stock at the original exercise price of $2.546 per share, issued on August 11, 2022 (the "Existing PIOs"). Pursuant to the Inducement Letter, the Holder agreed to exercise for cash its Existing PIOs to purchase an aggregate of 2,486,214 shares of the Company's common stock (the "Inducement PIO Shares"), at a reduced exercised price of $1.09 per share, in exchange for the Company's agreement to issue new preferred investment options (the "Inducement PIOs") to purchase up to 4,972,428 shares of the Company's common stock. The Inducement PIOs have substantially the same terms as the Existing PIOs.

On August 2, 2023, the Company consummated the transactions contemplated by the Inducement Letter (the "Warrant Inducement"). The Company received aggregate net proceeds of approximately $2.3 million from the Warrant Inducement, after deducting placement agent fees and other offering expenses payable by the Company.

Upon the close of the transaction, the Company issued the Holder 1,575,000 of the 2,486,214 shares of common stock that were issuable upon exercise of the Existing PIOs. Due to the beneficial ownership limitation provisions in the Inducement Letter, the remaining 911,214 shares were initially unissued, and held in abeyance for the benefit of the Holder until notice from the Holder that the shares may be issued in compliance with such limitation is received. These shares were issued to the Holder in October 2023.

Note 8 — Stockholders' Equity (cont.)

The Company agreed to file a registration statement covering the resale of the Inducement PIO Shares issued or issuable upon the exercise of the Inducement PIOs (the "Resale Registration Statement"), as soon as practicable, and to use commercially reasonable efforts to have such Resale Registration Statement declared effective by the SEC within 90 days following the date of the Inducement Letter, and to keep the Resale Registration Statement effective at all times until there are no Inducement PIO Shares. The provision to register the underlying shares in the Warrant Inducement does not require payment related to the registration rights provided. As such, while the shares were not registered within 90 days of the date of the Inducement Letter, there is no accounting impact for this provision.

The Company engaged Wainwright to act as its placement agent in connection with the Warrant Inducement and paid Wainwright a cash fee equal to 7.5% of the gross proceeds received from the exercise of the Existing PIOs as well as a management fee equal to 1.0% of the gross proceeds from the exercise of the Existing PIOs. The Company also agreed to reimburse Wainwright for its expenses in connection with the exercise of the Existing PIOs and the issuance of the Inducement PIOs, up to $50,000 for fees and expenses of legal counsel and other out-of-pocket expenses and agreed to pay Wainwright for non-accountable expenses in the amount of $35,000. In addition, the exercise for cash of the Existing PIOs triggered the issuance to Wainwright or its designees, warrants to purchase 149,173 shares of common stock ("Wainwright Inducement Warrants"), which were issuable in accordance with the terms of the August Contingent Warrants, and have the same terms as the Inducement PIOs except for an exercise price equal to $1.3625 per share. The Company also agreed to issue warrants to Wainwright upon any exercise for cash of the Inducement PIOs, that number of shares of common stock equal to 6.0% of the aggregate number of such shares of common stock underlying the Inducement PIOs that have been exercised, also with an exercise price of $1.3625 (the "Inducement Contingent Warrants"). The maximum number of Inducement Contingent Warrants issuable under this provision is 298,346.

The Company evaluated the terms of the Inducement PIOs and the Wainwright Inducement Warrants (collectively, the "August 2023 Inducement Warrants"), and determined that they should be classified as equity instruments based upon accounting guidance provided in ASC 480 and ASC 815-40. The Company also evaluated the unissued shares held in abeyance, which represent a prepaid forward contract, and determined that it is an equity instrument based on the guidance provided in ASC 480 and ASC 815-40.

The Warrant Inducement, which resulted in the lowering of the exercise price of the Existing PIOs and the issuance of the Inducement PIOs, is considered a modification of the Existing PIOs under the guidance of Accounting Standards Update ("ASU") No. 2021-04, *Issuer's Accounting for Certain Modifications or Exchanges of Equity Classified Written Call Options*. The modification is consistent with the "Equity Issuance" classification under that guidance as the reason for the modification was to induce the holders of the Existing PIOs to cash exercise their warrants, resulting in the imminent exercise of the Existing PIOs, which raised equity capital and generated net proceeds for the Company of approximately $2.3 million. As the Existing PIOs and the Inducement PIOs 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 modification of approximately $2.6 million as an equity issuance cost.

In addition, the change in fair value of the contingent warrant liability associated with 149,173 of the August Contingent Warrants that were settled through issuance of the Wainwright Inducement Warrants, of approximately $122,000, was recognized in other income (expense) in the accompanying condensed statements of operations, and the fair value of the contingent warrant liability of approximately $129,000 was derecognized as of the settlement date. The corresponding amount, representing the fair value of the Wainwright Inducement Warrants, was recognized as additional paid in capital.

Note 8 — Stockholders' Equity (cont.)

The Company evaluated the terms of the Inducement Contingent Warrants and determined that they should be classified as a liability based upon accounting guidance provided in ASC 815-40. Since the Inducement Contingent Warrants are a form of compensation to Wainwright, the Company recorded the value of the liability of approximately $26,000 as a reduction of additional paid in capital, with subsequent changes in the value of the liability recorded in other income (expense) in the accompanying condensed statements of operations.

Warrants

The following summarizes activity related to the Company's outstanding warrants, excluding contingent warrants issuable upon exercise of the preferred investment options, for the nine months ended September 30, 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	5,121,601	1.10	
Exercised	(3,132,854)	0.865	
Cancelled	—	—	
Outstanding as of September 30, 2023	7,899,661	1.68	4.6
Warrants vested and exercisable as of September 30, 2023	7,899,661	$ 1.68	4.6

As of September 30, 2023, the outstanding warrants include 70,849 April 2022 Private Placement Warrants, 2,707,211 August 2022 Private Placement Warrants, and 5,121,601 August 2023 Inducement Warrants, which are exercisable into 7,899,661 shares of common stock which had a fair value of $0.51 per share, based on the closing trading price on that day.

Additionally, as of September 30, 2023, and December 31, 2022, the value of the August Contingent Warrants and the Inducement Contingent Warrants (collectively the "Contingent Warrants") was approximately $10,000 and $14,000, respectively. The maximum number of warrants issuable upon settlement of the Contingent Warrants as of September 30, 2023 and December 31, 2023 was 447,519 and 298,346, respectively.

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.

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 and in May 2023, the number of shares of common stock reserved for issuance under the 2022 Plan was increased to 3,150,000. The stock options and restricted stock granted during the nine months ended September 30, 2023 were all granted under the 2022 Plan. As of September 30, 2023, there are 1,146,878 shares available for issuance under the 2022 Plan.

Note 8 — Stockholders' Equity (cont.)

Stock Options

The following summarizes activity related to the Company's stock options under the 2019 Plan and the 2022 Plan for the nine months ended September 30, 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	(70,265)	3.35	—	—
Exercised	(45,920)	0.01	45,920	—
Outstanding as of September 30, 2023	1,378,855	3.25	274,299	7.8
Options vested and exercisable as of September 30, 2023	1,094,563	$ 2.95	$ 269,994	7.5

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

	For the Nine Months Ended September 30, 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 nine months ended September 30, 2023 was $1.08. The aggregate fair value of stock options that vested during the three and nine months ended September 30, 2023 was approximately $137,000 and $616,000, respectively.

Restricted Stock

On May 9, 2023, the Board'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 Chief Executive Officer ("CEO"), Chief Financial Officer, and Chief Business Officer, respectively. All of the restricted shares granted vest as follows: 50% in January 2024, 25% in August 2024, and 25% in August 2025. In addition, on May 31, 2023, the Board's Compensation Committee approved the issuance of 25,440 shares of restricted stock, granted to the Company's non-executive Board members, with full vesting on May 31, 2024.

Note 8 — Stockholders' Equity (cont.)

On August 16, 2023, upon his resignation, the Company's former Chief Executive Officer forfeited 150,000 shares of unvested restricted stock.

	Number of Shares	Weighted Average Weighted Average Grant Date Fair Value
Nonvested as of December 31, 2022	—	$ —
Granted	512,940	1.01
Forfeited / cancelled	(168,860)	1.02
Vested	—	—
Nonvested as of September 30, 2023	344,080	$ 1.01

Stock-Based Compensation

Stock-based compensation expense related to stock options and restricted stock, for the three and nine months ended September 30, 2023, and 2022 was as follows:

	For the Three Months Ended September 30,		For the Nine Months Ended September 30,	
	2023	2022	2023	2022
Selling, general and administrative	$ 89,832	$ 255,115	$ 362,191	$ 1,193,743
Research and development	15,570	74,694	201,570	602,525
Total	**$ 105,402**	**$ 329,809**	**$ 563,761**	**$ 1,796,268**

As of September 30, 2023, unrecognized stock-based compensation expense relating to outstanding stock options and unvested restricted stock is approximately $394,000 and $143,000, respectively, which is expected to be recognized over a weighted-average period of 1.67 years and 1.49 years, respectively.

Note 9 — 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 former CEO, ended on April 30, 2023. During the nine months ended September 30, 2023, the Company incurred rent expense on this lease of approximately $51,000, and variable lease expense of approximately $4,000. The Company incurred rent expense for the three and nine months ended September 30, 2022 of approximately $53,000 and $89,000, respectively.

Litigation

From time to time, the Company may be subject to various legal proceedings and claims that arise in the ordinary course of its business activities. As of September 30, 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 2022 Private Placement (see Note 8), 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 2022 Private Placement (see Note 8), 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 September 30, 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 September 30, 2023.

Note 9 — Commitments and Contingencies (cont.)

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 6). As of September 30, 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 September 30, 2023. Subsequent to the balance sheet date, the Company terminated two of these license agreements (see Note 14).

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 related to its indemnification obligations. However, during the third quarter of 2023, the Company received a claim from its former CEO and a former accounting employee requesting advancement of certain expenses, which may result in related expenses in the future. As of September 30, 2023, the Company recorded a related accrual of approximately $91,000, which is included in accrued expenses in the accompanying condensed balance sheet. The maximum potential amount of future payments the Company could be required to make under these indemnification agreements is not estimable at this time.

Note 10 — Related Party Transactions

The Company originally engaged the former CEO, who was 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 former CEO's employment agreement became effective. During the nine months ended September 30, 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 former CEO. The lease expired on April 30, 2023 (see Note 9).

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 former 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 nine months ended September 30, 2022, as selling, general and administrative expenses in the accompanying condensed statement of operations.

During the three and nine months ended September 30, 2023, the Company's Audit Committee completed a review of the Company's expenses due to certain irregularities identified with regards to the related party balance. Based on the results of the review, it was determined that the Company paid and recorded within selling, general and administrative expense personal expenditures of the Company's former CEO and an accounting employee who was also the former CEO's assistant, during 2022 and during the first three quarters of 2023. The Company evaluated the receivable, which aggregates to approximately $522,000 as of September 30, 2023, and which represents the total of the items identified as personal in nature for which the Company does not anticipate recovery from the related party. The Company recorded a corresponding reserve for the full amount, resulting in a net related party receivable balance of $0 as of September 30, 2023. As the Company concluded that the amounts are not likely to be recovered, this would not cause an adjustment to previously issued financial statements.

Further, the credit card misuse described above resulted in a loss on related party receivable of approximately $100,000 and $266,000 during the three and nine months ended September 30, 2023, respectively, which was recorded in selling, general, and administrative expenses in the accompanying statements of operations.

Note 10 — Related Party Transactions (cont.)

As of December 31, 2022, the Company had a receivable from related party of approximately $36,000, consisting of miscellaneous payments made by the Company on the behalf of the Company's former CEO, and which was paid in full during the first quarter of 2023.

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 6. This director resigned from the Board upon the close of the IPO, and also resigned from the Scientific Advisory Board on August 28, 2023.

Note 11 — Income Taxes

No provision for federal, state or foreign income taxes has been recorded for the three and nine months ended September 30, 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 and nine months ended September 30, 2023, and 2022, the Company has not recognized any interest or penalties related to income taxes.

Note 12 — Net Loss Per Share

Basic net 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. The weighted average number of shares of common stock outstanding includes (i) pre-funded warrants because their exercise requires only nominal consideration for delivery of shares, and (ii) the shares held in abeyance because there is no consideration required for delivery of the shares; it does not include any potentially dilutive securities or any unvested restricted shares of common stock. Certain restricted shares, although classified as issued and outstanding at September 30, 2023, are considered contingently returnable until the restrictions lapse and will not be included in the basic net loss per share calculation until the shares are vested. Unvested shares of the Company's restricted stock do not contain non-forfeitable rights to dividends and dividend equivalents. 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, options, and restricted shares. Diluted net loss per share is computed by giving effect to all potential shares of common stock, including warrants, stock options, and unvested restricted shares, to the extent they are dilutive.

The two-class method is used to determine earnings per share based on participation rights of participating securities in any undistributed earnings. Each share of 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 and Nine Months Ended September 30,	
	2023	**2022**
Unvested shares of restricted stock	344,080	—
Options to purchase shares of common stock	1,378,855	1,383,801
Warrants	7,899,661	5,375,385
Total	**9,622,596**	**6,759,186**

Note 13 — Retirement Plan

On May 31, 2023, the Board voted to adopt a 401(k) Safe Harbor Non-Elective Plan (the "401(k) Plan"). The 401(k) Plan was an employee savings and retirement plan to which substantially all employees could have contributed, including the Company's named executive officers, effective July 1, 2023. Pursuant to the 401(k) Plan, employee and Company contributions would vest immediately, subject to a three-month waiting period for new hires. The Company was required to contribute 3% of gross pay to eligible employees' 401(k) Plans. On November 16, 2023, the 401(k) Plan was terminated.

Note 14 — Subsequent Events

Veru APA Amendment

On October 3, 2023, in accordance with the terms of the Veru APA Amendment, the Company issued 3,000 shares of Series A Preferred Stock to Veru as settlement for the $3,000,000 note payable that had an original maturity date of September 30, 2023 (see Note 5).

WraSer APA Amendment

On October 4, 2023, the parties agreed to amend the WraSer APA, which is subject to court approval. Shortly after its bankruptcy filing, WraSer filed a motion seeking approval of the WraSer APA as amended. The amendment, among other things, eliminates the $500,000 post-closing payment due June 13, 2024 and staggers the $4.5 million cash payment that the Company would otherwise have to pay at closing to: (i) $2.2 million to be paid at closing, (ii) $2.3 million, to be paid in monthly installments of $150,000 commencing January 2024 and (iii) 789 shares of Series A Preferred Stock to be paid at closing. The amendment also reduced the number of products we were acquiring by excluding pain medications and including only (i) Ciprofloxacin 0.3% and Fluocinolone 0.025% Otic Solution, under the trademark OTOVEL and its Authorized Generic Version approved under US FDA NDA No. 208251, (ii) Ciprofloxacin 0.2% Otic solution, under the trademark CETRAXAL, and (iii) Vorapaxar Sulfate tablets under the trademark Zontivity approved under US FDA NDA N204886.

On October 6, 2023, the Company was alerted to certain issues in WraSer's operations relating to WraSer's inability to manufacture the active pharmaceutical ingredient for one of the key WraSer Assets, which development, the Company believes, constitutes a Material Adverse Effect (as such term is defined in the WraSer APA) that will prevent the Company from closing the transaction. On October 20, 2023, the Company filed a motion for relief from the automatic stay in the Bankruptcy Court so that we can exercise our termination rights under the WraSer APA, as amended. WraSer has advised the Company that it does not believe that a Material Adverse Event occurred. If the Bankruptcy Court does not grant the Company's motion and requires it to complete the transaction, the Company will not be able to execute its commercialization strategy for the WraSer Assets because there is no manufacturer for the active pharmaceutical ingredient for Zontivity, the key driver for the WraSer acquisition. Due to the WraSer bankruptcy filing and the Company's status as an unsecured creditor of WraSer, it is unlikely that the Company will recover the $3.5 million initial payment made or any costs and resources in connection with services provided by the Company under the WraSer MSA. If the Company does not complete the purchase of the WraSer Assets and the WraSer APA is terminated, the Company will not be able to recover any such costs. Any claims the Company makes for such payment will be general unsecured claims (see Note 5).

Note 14 — Subsequent Events (cont.)

Chief Financial Officer Separation Agreement

Effective as of October 4, 2023, Jon Garfield resigned as Chief Financial Officer of the Company. The Company and Mr. Garfield entered into a separation agreement, which provides for a two-month severance payment.

Equity Incentive Plan Activity

On October 4, 2023, the Company's Board granted stock options to the Company's newly hired Chief Executive Officer and Chief Financial Officer. The options granted to the Chief Executive Officer and Chief Financial Officer totaled 532,326 and 177,442, respectively, have an exercise price of $0.4305 per share, and vest quarterly over a three-year period.

On October 4, 2023, upon his resignation, the Company's former Chief Financial Officer forfeited 75,000 shares of unvested restricted stock, and 50,000 stock options.

Services Agreement

On October 12, 2023, the Company terminated a Master Services Agreement and statements of work with a vendor, resulting in early termination fees of approximately $2.3 million. The Company will record these fees during the quarter ending December 31, 2023 (see Note 6).

License Terminations

On November 15, 2023, the Company informed Oxford University Innovation and St. Jude of its termination of the respective license agreements (see Note 6). The amounts due upon termination of these license agreements were not significant.

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 commercial stage biotechnology company focused on the research, development, and commercialization of innovative solutions for oncology. We own ENTADFI®, an FDA-approved, once daily pill that combines finasteride and tadalafil for the treatment of benign prostatic hyperplasia ("BPH"), a disorder of the prostate. 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. Following a recent business strategy shift towards the field of oncology and deprioritization of preclinical vaccine programs, we are building additional assets in therapeutics, diagnostics, and clinician services for oncology. ENTADFI® will become the inaugural therapeutic drug in the Company's expanding portfolio of oncology therapeutics once launched.

Prior to the acquisition of ENTADFI®, we managed one distinct business segment, which was research and development. Beginning in the second quarter of 2023, as a result of the acquisition of ENTADFI®, for which we are working towards commercial launch, we operated in two business segments: research and development and commercial. During the third quarter of 2023, we deprioritized our vaccine discovery and development programs, and accordingly, we now operate in one segment: commercial. The research and development segment was our historical business, and was dedicated to the research and development of various vaccines to prevent infectious diseases. The commercial segment was new in the second quarter of 2023 and is dedicated to the commercialization of our FDA-approved products, this currently being ENTADFI®.

Since June 30, 2023, some key developments affecting our business include:

- ***Announced Shift in Business Strategy to Focus on the Field of Oncology:*** On October 30, 2023, in a letter to shareholders, President and CEO, Dr. Neil Campbell, announced that the Company intends to shift its focus toward building a foundation of therapeutic, diagnostic, and service products in the field of oncology. The Company's previous activities in acquiring assets from WraSer and Xspire Pharma, including certain commercial relationships intended for the marketing and sale of these assets, were reassessed and it was decided that they would not align with the new shift towards oncology. Additionally, the Company conducted a strategic and tactical assessment of its preclinical vaccine programs and, considering the immense amount of time and resources needed to pursue these programs as well as evolving market dynamics, these programs have been deprioritized. The Company believes that the strategic shift in business strategy towards the field of oncology, as well as pursuing the launch of Entadfi® in 2024, will enhance shareholder value and enable the Company to provide leading-edge therapeutics, diagnostics, and services to clinicians, patients, and caregivers.

- ***Signed Non-Binding Term Sheet to Acquire a Commercial Stage Oncology Company:*** On November 2, 2023, the Company announced the execution of a non-binding term sheet regarding the acquisition of a private commercial stage oncology biotechnology company (the "Proposed Transaction"). This announcement furthers a shift in business strategy driven by the Company's decision to align with both the market value drivers provided by its new oncology focus and the extensive life sciences company-building expertise of its new leadership team. After stockholder approval of the Proposed Transaction, shareholders of the target company will own a majority of the Company. The Company expects to announce additional details regarding the Proposed Transaction when a definitive agreement is executed. The completion of the transaction is subject to, among other matters, the completion of due diligence, the negotiation of a definitive agreement, obtaining adequate financing, satisfaction of the conditions negotiated therein and approval of the Proposed Transaction by the board and stockholders, as and when applicable. There can be no assurance that a definitive agreement will be entered into or that the Proposed Transaction will be consummated on the terms or timeframe currently contemplated, or at all.

- ***Dr. Neil Campbell appointed as CEO and President and a member of the Board:*** On October 4, 2023, Dr. Neil Campbell was appointed as CEO and President and a member of the Board. Dr. Campbell has over 30 years of successful experience with public and private companies in the life sciences, medical, healthtech, nanotechnology, artificial intelligence, and high-performance computing technologies. Previously, Dr. Campbell was Chairman, CEO, and founder of Celios, a respiratory and therapeutic device. Prior to founding Celios, Dr. Campbell was co-founder, President and CEO of Helomics, a personalized healthcare company focused on next-generation oncology therapeutics and diagnostics. Dr. Campbell has prior institutional investment experience as a partner in venture capital, and operating partner and industry advisor in private equity. Dr. Campbell has also held senior executive positions at SuperNova Diagnostics, EntreMed Pharmaceuticals, Life Technologies, IGEN International (now Roche), Celera Genomics, and Abbott Laboratories. Dr. Campbell has also held academic positions at Johns Hopkins University and Medical Institutes, Hong Kong University of Science and Tech (HKUST), University of Liverpool (UK), University of Baltimore and Duquesne University. Dr. Campbell is a veteran of the U.S. Air Force. Dr. Campbell received his B.S. from Norwich University, M.A. and M.B.A. from Webster University and Doctorate from the University of Liverpool in the United Kingdom.

- ***Bruce Harmon appointed as CFO:*** On October 4, 2023, Bruce Harmon was appointed as Chief Financial Officer. Mr. Harmon has over 40 years of experience as a financial professional, with more than 30 years serving as a controller, chief financial officer, director, audit chairman, and as a consultant providing CFO services primarily to publicly traded companies. Mr. Harmon has served as CFO of Marizyme, Inc. from 2020 through 2021, as CFO of bioAffinity Technologies, Inc. in 2022, a director for Dale Biotech LLC since 2017, and as a director of Patriax Industries™ since 2023. Mr. Harmon has, through his consulting firm, Lakeport Business Services, Inc., worked with more than 150 clients since 2008, primarily providing CFO services. Mr. Harmon has extensive experience with fund raising, mergers and acquisitions, and turnarounds. Mr. Harmon has been a key person in the public registration of 15 companies, including an IPO to The Nasdaq Stock Market LLC ("Nasdaq"). Mr. Harmon was part of a three-person team that, at the invitation of the Environmental Programmé, presented a green building product to 84 delegates at the United Nations in 2008. Mr. Harmon has an accounting degree from Missouri State University.

- ***Regained Compliance with Nasdaq Listing Rule 5250(c)(1):*** On November 1, 2023, the Company announced that it had regained compliance with Nasdaq Listing Rule 5250(c)(1) ("The Rule"). The Rule requires listed companies to timely file all required periodic financial reports with the Securities and Exchange Commission ("SEC"). On October 20, 2023, the Company filed its Form 10-Q for the period ended June 30, 2023. We are not currently in compliance with Nasdaq Listing Rule 5550(a)(2) (the "Bid Price Rule"). We have 180 days from September 18, 2023, or through March 16, 2024, to regain compliance with the Bid Price Rule.

- ***Signed Various Agreements to Support the Commercial Launch of ENTADFI®:*** Throughout the third quarter of 2023, the Company signed several agreements and established key relationships to support the commercial launch of ENTADFI®. These agreements include the following:

  - ***Marketing and Advertising Support:*** In July 2023, the Company signed a Master Services Agreement with bfw Advertising Inc. ("bfw") to generate marketing and advertising material for Blue Water's commercial stage drug portfolio. Bfw will work with Blue Water's commercial team to increase awareness for its commercial products through patient-facing materials, website updates, social ads, targeted provider engagement, as well as materials to support Blue Water's sales team, among other services.

  - ***Healthcare Payer Coverage Support:*** In July 2023, Blue Water signed an agreement with Advantage Point Solutions, LLC ("APS") to support Blue Water's market access strategy for its commercial pharmaceutical portfolio. APS will support market access for ENTADFI®, including assistance in formulary negotiations with key healthcare payers and pharmacy benefit managers in the commercial and government sectors. With its robust network of relationships, APS helps commercial stage pharmaceutical companies build long-term relationships with payers with the goal of maximizing access and reimbursement for approved pharmaceutical products. APS also has decades of experience advising companies on product launches across a broad spectrum of therapeutic areas.

  - ***Telemedicine Channel:*** In July 2023, Blue Water signed an agreement with UpScriptHealth to generate a robust, online telemedicine platform to distribute ENTADFI®. Through this platform, UpScriptHealth will help support patients with benign prostatic hyperplasia throughout the prescription and coverage process, as well as provide eligible patients access to ENTADFI® mailed directly to their homes.

  - ***Entered into Distribution Agreement***: On September 21, 2023, the Company entered into an Exclusive Distribution Agreement to engage Cardinal Health 105, LLC as its exclusive third-party logistics distribution agent for sales of all of the Company's commercial assets.

- ***Granted Pharmaceutical Wholesaler License in Ohio and Tennessee:*** The Ohio State Board of Pharmacy and the Tennessee State Board of Pharmacy, in July 2023 and September 2023, respectively, granted Blue Water a license to operate as a pharmaceutical wholesaler. These licenses allow Blue Water to conduct business in the States of Ohio and Tennessee.

Since our inception in October 2018 until April 2023, when we acquired ENTADFI®, we 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 now deprioritized vaccine candidates, organizing and staffing our company, performing business planning, establishing our intellectual property portfolio and raising capital to support and expand such activities.

Since our April 2023 acquisition of ENTADFI®, we have been focusing our efforts on building out our commercial capabilities to launch ENTADFI® in the marketplace.

Given ENTADFI® is currently FDA-approved, we expect to generate revenue from sales of ENTADFI® in the near term. Although we anticipate these sales to offset some expenses relating to commercial scale up and development, we expect our expenses will increase substantially in connection with our ongoing activities, as we:

- Commercialize and launch ENTADFI®, and other commercial-stage products,
- hire additional personnel;
- operate as a public company, and;
- obtain, maintain, expand and protect our intellectual property portfolio.

We rely and will continue to rely on third parties for the manufacturing of 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 commercial products.

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. We also expect to incur significant commercialization expenses related to marketing, manufacturing and distribution for those products.

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, the close of the 2022 Private Placements, and the proceeds received from a warrant exercise in August 2023. We will continue to require significant additional capital to commercialize ENTADFI® and fund operations for the foreseeable future. Accordingly, until such time as we can generate significant revenue, if ever, we expect to finance our cash needs through public or private equity or debt financings, third-party (including government) funding and to rely on third-party resources for marketing and distribution arrangements, as well as other collaborations, strategic alliances and licensing arrangements, or any combination of these approaches, to support our operations.

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 September 30, 2023, the Company had a working capital deficit of approximately $8.1 million and an accumulated deficit of approximately $34.4 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.

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 condensed financial statements do not include any adjustment that might be necessary if the Company is unable to continue as a going concern.

Because of the numerous risks and uncertainties associated with our business, 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. Additionally, even if we are able to generate revenue from 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.

Management and Board Changes

Effective as of August 16, 2023, Joseph Hernandez resigned as Chairman, Chief Executive Officer, and a member of the Board of Directors (the “Board”) of the Company.

Effective August 16, 2023, the Board appointed Jon Garfield, the Company’s former Chief Financial Officer, to serve as the Company’s interim principal executive officer. Effective as of October 4, 2023, Jon Garfield resigned as Chief Financial Officer of the Company. The Company and Mr. Garfield entered into a separation agreement, which provides for two months of severance payment.

Effective as of September 2, 2023, Vuk Jeremic resigned as a member of the Board of the Company as well as from his positions as a member of the Compensation Committee and Nominating and Corporate Governance Committee of the Board. Mr. Jeremic’s departure was not the result of any disagreement with management or the Board on any matter relating to the Company’s operations, policies or practices.

On October 4, 2023 (the “Effective Date”), the Company appointed Dr. Neil Campbell, 63, as President and Chief Executive Officer of the Company and as a member of the Board of Directors (the “Board”) of the Company, effective immediately. As a Class III director, Dr. Campbell’s term lasts until the Company’s 2024 annual meeting of stockholders.

Dr. Campbell’s appointment as President and Chief Executive Officer replaces the Company’s prior intentions for James Sapirstein to step in as Interim Executive Chairman. As previously disclosed in the Company’s Current Report on Form 8-K filed on August 22, 2023, Mr. Sapirstein served as Lead Independent Director during the Company’s search for a replacement for Joseph Hernandez. Mr. Sapirstein was originally intended to assume the position of Interim Executive Chairman on September 30, 2023. Instead, effective October 4, 2023, the Board elected Mr. Sapirstein as non-executive Chairman of the Board. Mr. Sapirstein will continue to serve as Lead Independent Director through October 31, 2023. In recognition of Mr. Sapirstein’s contributions to the Company as Lead Independent Director, the Board of Directors approved an increase in Mr. Sapirstein’s compensation for serving as Lead Independent Director from $25,000 to $40,000 per month for the period from August 2023 through October 2023.

In connection with Dr. Campbell's appointment, the Company and Dr. Campbell entered into an employment agreement (the "Campbell Employment Agreement"), pursuant to which Dr. Campbell will serve as President and Chief Executive Officer of the Company and will be paid a signing bonus of $75,000 and an annual base salary of $475,000. In addition, Dr. Campbell is entitled to receive, subject to employment by the Company on the applicable date of bonus payout, an annual target discretionary bonus of up to 50% of his annual base salary, payable at the discretion of the Compensation Committee of the Board. Dr. Campbell is also eligible to receive healthcare benefits as may be provided from time to time by the Company to its employees generally, and to receive paid time off annually. Pursuant to the Campbell Employment Agreement, Dr. Campbell was granted a long-term equity incentive grant in the form of an option to purchase 3% of the total outstanding shares of the Company's common stock as of the Effective Date. Such award vests in quarterly increments over a period of three years from the Effective Date, subject to Dr. Campbell's continued employment by the Company on the applicable vesting date. Dr. Campbell's option grant has an exercise price per share equal to $0.4305, which was the closing price of the Company's common stock on Nasdaq on the grant date.

On the Effective Date, the Company also appointed Bruce Harmon, 65, as Chief Financial Officer of the Company, effective immediately.

In connection with Mr. Harmon's appointment, the Company and Mr. Harmon entered into an employment agreement (the "Harmon Employment Agreement"), pursuant to which Mr. Harmon will serve as Chief Financial Officer of the Company and will be paid an annual base salary of $325,000. In addition, Mr. Harmon is entitled to receive, subject to employment by the Company on the applicable date of bonus payout, an annual target discretionary bonus of up to 30% of his annual base salary, payable at the discretion of the Compensation Committee of the Board. Pursuant to the Harmon Employment Agreement, Mr. Harmon is also eligible to receive healthcare benefits as may be provided from time to time by the Company to its employees generally, and to receive paid time off annually. Pursuant to the Harmon Employment Agreement, Mr. Harmon was granted a long-term equity incentive grant in the form of an option to purchase 1% of the total outstanding shares of the Company's common stock as of the Effective Date. Such award vests in quarterly increments over a period of three years from the Effective Date, subject to Mr. Harmon's continued employment by the Company on the applicable vesting date. Mr. Harmon's option grant has an exercise price per share equal to $0.4305, which was the closing price of the Company's common stock on Nasdaq on the grant date.

Recent Acquisitions:

ENTADFI®

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

The Company purchased substantially all of Veru'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.

Pursuant to the terms of the Veru APA, the Company agreed to provide Veru 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. On September 29, 2023, the Company entered into an amendment (the "Amendment") of the Veru APA. Pursuant to the Amendment, the $4.0 million note payable originally due on September 30, 2023, was deemed paid and fully satisfied upon (1) the payment to Veru of $1 million in immediately available funds on September 29, 2023, and (2) the issuance to Veru by October 3, 2023 of 3,000 shares of Series A Preferred Stock of the Company.

The terms of the Series A Preferred Stock are set forth in the Certificate of Designations, which was filed with the State of Delaware on September 29, 2023. Pursuant to the Certificate of Designations, each share of Series A Preferred Stock will convert one year from the date of issuance of the Series A Preferred Stock into that number of shares of the Company's common stock determined by dividing the Stated Value (as defined in the Certificate of Designations) of $1,000 per share by the Conversion Price (as defined in the Certificate of Designations) of $0.5254 per share, subject to adjustment as provided in the Certificate of Designations, subject to certain shareholder approval limitations. The Series A Preferred Stock is entitled to share ratably in any dividends paid on the Company's common stock (on an as-if-converted-to-common-stock basis), has no voting rights except as to certain significant matters specified in the Certificate of Designations, and has a liquidation preference equal to the Stated Value of $1,000 per share plus any accrued but unpaid dividends thereon. The Series A Preferred Stock is redeemable in whole or in part at the Company's option at any time. The Certificate of Designations authorized the issuance of up to 10,000 shares of Series A Preferred Stock.

The Series A Preferred Stock issued to Seller is initially convertible, in the aggregate, into approximately 5,709,935 shares of the Company's common stock, subject to adjustment and certain shareholder approval limitations specified in the Certificate of Designations. Pursuant to the Amendment, the Company agreed to use commercially reasonable efforts to obtain such shareholder approval by December 31, 2023. The Company also agreed to include the shares of common stock issuable upon conversion of the Series A Preferred Stock in the next resale registration statement filed with the SEC.

Additionally, the terms of the Veru APA require the Company to pay Veru 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.

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 Veru 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 as follows: (i) $5.0 million is payable upon the first time the Company achieves net sales from ENTADFI® of $100.0 million during a calendar year, (ii) $7.5 million is payable upon the first time the Company achieves net sales from ENTADFI® of $200.0 million during a calendar year, and (3) $10.0 million is payable upon the first time the Company achieves net sales from ENTADFI® of $300.0 million during a calendar year.

WraSer (Acquisition closing pending as of September 30, 2023)

On June 13, 2023 (the "Execution Date"), the Company entered into an asset purchase agreement with WraSer, LLC, a Mississippi limited liability company, Xspire Pharma, LLC, a Mississippi limited liability company (collectively, the "Seller"), and Legacy-Xspire Holdings, LLC, a Delaware limited liability company and the parent company of the Seller ("Parent") (the "WraSer APA"). Pursuant to, and subject to the terms and conditions of, the WraSer APA, on the Closing Date (as defined below) the Company will purchase six FDA-approved pharmaceutical assets across several indications, including cardiology, otic infections, and pain management (the "WraSer Assets").

Under the terms of the WraSer APA, the Company will purchase the WraSer Assets for (i) $3.5 million in cash at signing of the WraSer APA; (ii) $4.5 million in cash on the later of (x) 90 days after the signing of the WraSer APA or (y) the date that all closing conditions under the WraSer APA are met or otherwise waived (the "Closing Date"); (iii) 1.0 million shares of the Company's common stock (the "Closing Shares") issuable on the Closing Date, and (iv) $500,000 in cash one year from the Closing Date. The closing of the transaction is subject to certain customary closing conditions and the delivery to the Company of financial statements of Seller and Parent for the fiscal years ended December 31, 2022 and 2021 audited by a qualified auditor reasonably acceptable to the Company.

Within 90 days of the Closing Date, the Company will use its best efforts to file with the SEC, (at its sole cost and expense,) a registration statement to register on Form S-3 registering under the Securities Act of 1933, as amended (the "Securities Act"), the resale of the Closing Shares and will use its best efforts to have the registration statement declared effective as soon as practicable after filing.

In conjunction with the WraSer APA, the Company and the Seller entered into a Management Services Agreement (the "MSA") on the Execution Date. Pursuant to the terms of the MSA, the Company will act as the manager of the Seller's business during the period between the Execution Date and Closing Date. During this period, the Company will make advances to WraSer, if needed to sustain operations. The Company's involvement as manager of the Seller's business ended when WraSer filed for relief under chapter 11 of the U.S. Bankruptcy Code in the Bankruptcy Court (see below). If, on the Closing Date, the Seller's cash balance is in excess of the target amount specified in the MSA of $1.1 million (the "Cash Target"), the Company will apply that excess to the $4.5 million cash payment due upon closing. Conversely, if there is a shortfall, the Company will be required to remit the difference to the Seller over time. Specifically, as the Company collects accounts receivable generated after the Closing Date, the Company will be required to remit 50% of the collections to the Seller until the shortfall is paid in full. The MSA terminates on the Closing Date.

The WraSer APA can be terminated prior to closing as follows (i) upon agreement with all parties; (ii) upon breach of contract of either party, uncured within 20 days of notice. If the WraSer APA is terminated upon agreement with all parties or upon uncured breach of contract by the Seller, the initial $3.5 million payment is retained by the Sellers. If it is determined that there is an uncured breach of contract by the Seller, and the WraSer APA is terminated, the Company will have an unsecured claim against WraSer for the $3.5 million payment made by the Company upon execution of the WraSer APA. The closing of the Transaction is subject to various closing conditions, including submission of the FDA transfer documentation to transfer ownership of the acquired product regulatory approvals to the Company.

On September 26, 2023, WraSer and its affiliates filed for relief under chapter 11 of the U.S. Bankruptcy Code in the Bankruptcy Court.

On October 4, 2023, the parties agreed to amend the WraSer APA. Shortly after its bankruptcy filing, WraSer filed a motion seeking approval of the WraSer APA as amended. The amendment, among other things, eliminates the $500,000 post-closing payment due June 13, 2024 and staggers the $4.5 million cash payment that the Company would otherwise have to pay at closing to: (i) $2.2 million to be paid at closing, (ii) $2.3 million, to be paid in monthly installments of $150,000 commencing January 2024 (the "Post-Closing Payment") and (iii) 789 shares of Series A Preferred Stock to be paid at closing. The amendment also reduced the number of products we were acquiring by excluding pain medications and including only (i) Ciprofloxacin 0.3% and Fluocinolone 0.025% Otic Solution, under the trademark OTOVEL and its Authorized Generic Version approved under US FDA NDA No. 208251, (ii) Ciprofloxacin 0.2% Otic solution, under the trademark CETRAXAL, and (iii) Vorapaxar Sulfate tablets under the trademark Zontivity approved under US FDA NDA N204886.

On October 6, 2023, we were alerted to certain developments in WraSer's operations relating to WraSer's inability to manufacture the active pharmaceutical ingredient for one of the key WraSer Assets, which development we believe constitutes a Material Adverse Effect (as such term is defined in the WraSer APA) that will prevent us from closing the transaction. On October 20, 2023, we filed a motion for relief from the automatic stay in the Bankruptcy Court so that we can exercise our termination rights under the WraSer APA, as amended. WraSer has advised us that it does not believe that a Material Adverse Event occurred. If the Bankruptcy Court does not grant our motion and requires us to complete the transaction, we will not be able to execute our commercialization strategy for the WraSer Assets because there is no manufacturer for the active pharmaceutical ingredient for Zontivity, the key driver for the WraSer acquisition. Due to the WraSer bankruptcy filing and our status as an unsecured creditor of WraSer, it is also unlikely that we will recover the $3.5 million initial payment made or any costs and resources in connection with services provided by the Company under the WraSer MSA. In addition, if the WraSer APA is terminated, we will not be able to recover any such costs.

Agreement with Cardinal Health

On September 21, 2023, the Company entered into an Exclusive Distribution Agreement (the "Exclusive Distribution Agreement"), effective as of September 20, 2023 (the "Effective Date"), with Cardinal Health 105, LLC ("Cardinal Health"). Pursuant to, and subject to the terms and conditions of, the Exclusive Distribution Agreement, the Company engaged Cardinal Health as its exclusive third-party logistics distribution agent for sales of all of the Company's commercial assets. The term of the Distribution Agreement is three years from the Effective Date and automatically renews for additional terms of one year each unless terminated pursuant to the terms of the Exclusive Distribution Agreement. Under the terms of the Exclusive Distribution Agreement, the Company must pay to Cardinal Health a one-time start-up fee of $15,500, a monthly account management fee of $7,000, and other fees for various services, including post-launch program implementation, information systems, warehouse operations, and financial services.

Corporate Name Change and Amendment to Bylaws

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.

On May 31, 2023, the Board amended the Company's bylaws to reduce the quorum requirement at meetings of the Company's stockholders from a majority of the voting power of the outstanding shares of stock of the Company entitled to vote, to one-third of the voting power of the outstanding shares of stock of the Company entitled to vote, effective immediately. No other changes were made to the bylaws.

Warrant Inducement

On July 31, 2023, the Company entered into the Inducement Letter with the Holder of the Existing PIOs. Pursuant to the Inducement Letter, the Holder agreed to exercise for cash its Existing PIOs to purchase an aggregate of 2,486,214 shares of the Company's common stock, at a reduced exercise price of $1.09 per share, in exchange for the Company's agreement to issue Inducement PIOs to purchase up to 4,972,428 shares of the Company's common stock. The Inducement PIOs have substantially the same terms as the Existing PIOs. On August 2, 2023, the Company consummated the Warrant Inducement. The Company received aggregate net proceeds of approximately $2.3 million from the Warrant Inducement, after deducting placement agent fees and other offering expenses payable by the Company.

The Company engaged Wainwright to act as its placement agent in connection with the Warrant Inducement and paid Wainwright a cash fee equal to 7.5% of the gross proceeds received from the exercise of the Existing PIOs as well as a management fee equal to 1.0% of the gross proceeds from the exercise of the Existing PIOs. The Company also agreed to reimburse Wainwright for its expenses in connection with the exercise of the Existing PIOs and the issuance of the Inducement PIOs, up to $50,000 for fees and expenses of legal counsel and other out-of-pocket expenses and agreed to pay Wainwright for non-accountable expenses in the amount of $35,000. In addition, the exercise for cash of the Existing PIOs triggered the issuance to Wainwright or its designees, warrants to purchase 149,173 shares of common stock, which were issuable in accordance with the terms of Contingent Warrants issuable to Wainwright in connection with the August 2022 Private Placement Transaction, and have the same terms as the Inducement PIOs, except for an exercise price equal to $1.3625 per share. The Company also agreed to issue warrants to Wainwright upon any exercise for cash of the Inducement PIOs, that number of shares of common stock equal to 6.0% of the aggregate number of such shares of common stock underlying the Inducement PIOs that have been exercised, also with an exercise price of $1.3625. The maximum number of warrants issuable under this provision is 298,346.

Nasdaq Compliance

On September 18, 2023, we received notice from Nasdaq staff indicating that, based upon the closing bid price of the Common Stock for the prior 30 consecutive business days, we were not in compliance with the requirement to maintain a minimum bid price of $1.00 per share for continued listing on Nasdaq, as set forth in Nasdaq Listing Rule 5550(a)(2) (the "Bid Price Rule"). We have 180 days from September 18, 2023, or through March 16, 2024, to regain compliance with the Bid Price Rule.

On November 1, 2023, we announced that we had regained compliance with Nasdaq Listing Rule 5250(c)(1). The Rule requires listed companies to timely file all required periodic financial reports with the SEC. On October 20, 2023, the Company filed its Form 10-Q for the period ended June 30, 2023.

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 6 and 9 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 6 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 Notes 6 and 9 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 Notes 6 and 9 to our financial statements included elsewhere in this Report.

On November 15, 2023, the Company informed Oxford University Innovation of its termination of the OUI Agreement.

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 provided 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 provided 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 6 and 9 to our financial statements included elsewhere in this Report. On November 15, 2023, the Company informed St. Jude of its termination of the St. Jude Agreement.

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.

Services Agreement

On July 21, 2023, the Company, entered into Master Services Agreement and a related statement of work with a vendor, pursuant to which the vendor would provide to the Company commercialization services for the Company's products, including recruiting, managing, supervising and evaluating sales personnel and providing sales-related services for such products, for fees totaling up to $29.1 million over the term of the statement of work. The statement of work had a term through September 6, 2026, unless earlier terminated in accordance with the Master Services Agreement and the statement of work. On July 29, 2023, a second statement of work was entered into with the same vendor for certain subscription services providing prescription market data access to the Company. The fees under this statement of work total approximately $800,000, and the term was through July 14, 2025. As of September 30, 2023, the Company prepaid approximately $865,000 for commercialization services under the first statement of work. The Company also had approximately $898,000 recorded in related accounts payable as of September 30, 2023. As the prepayment can be applied against amounts invoiced from the vendor, the prepayment of approximately $865,000 has been offset against accounts payable in the accompanying condensed balance sheet. On October 12, 2023, the Company terminated the Master Services Agreement and statements of work, resulting in an early termination fee of approximately $2.3 million. The Company will record the early termination fee during the quarter ending December 31, 2023 (see Note 6).

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.

Components of Results of Operations

Research and Development Expenses

Substantially all of our research and development expenses have consisted 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 internal costs by product candidate, as a significant amount of research and development expenses include 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, which are not tracked by product candidate.

We expect our research and development expenses to increase, once research and development activities are resumed. 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.

Selling, General and Administrative Expenses

Selling, 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, and commercialization of ENTADFI®, including information technology costs, and other general operating expenses not otherwise classified as research and development expenses.

We anticipate that our selling, general and administrative expenses will continue to 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, along with costs for commercialization of products.

Results of Operations

Comparison of the Three Months Ended September 30, 2023 and 2022

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

	Three Months Ended September 30, 2023	Three Months Ended September 30, 2022	$ Change	% Change
Operating expenses				
Selling, general and administrative	$ 4,268,845	$ 2,694,254	1,574,591	58.4%
Research and development	219,238	1,175,480	(956,242)	(81.3)%
Total operating expenses	4,488,083	3,869,734	618,349	16.0%
Loss from operations	(4,488,083)	(3,869,734)	(618,349)	(16.0)%
Total other income (expense)	(858,825)	3,072	(861,897)	(28,056.5)%
Net loss	$ (5,346,908)	$ (3,866,662)	(1,480,246)	(38.3)%

Selling, General and Administrative Expenses

For the three months ended September 30, 2023, selling, general and administrative expenses increased by approximately $1.6 million compared to the same period in 2022. The increase was mainly due to increased commercialization activities for ENTADFI® of $1.7 million, an increase in professional fees of $0.6 million, an increase of $0.1 million in compensation expense primarily due to a reallocation of employee wages from research and development to selling, general and administrative expense, as a result of the shift in business focus towards commercialization, an impairment of long-lived assets of $0.3 million, and $0.1 million incurred for the loss on related party receivable. These increases were offset by a decrease of $0.8 million related to a loss contingency incurred in the three months ended September 30, 2022, with no similar expense in the current period, and a decrease in various business activities, such as business advisory services, travel related expenses, and rent expense, totaling $0.4 million.

Research and Development Expenses

For the three months ended September 30, 2023, research and development expenses decreased by approximately $1.0 million compared to the same period in 2022. The decrease was primarily due to the Company's decision to deprioritize its vaccine programs during the three months ended September 30, 2023.

Other Income (Expense)

Other expense incurred during the three months ended September 30, 2023, relates to $0.2 million of interest expense incurred on new notes payable issued in April 2023 related to the acquisition of ENTADFI® , a loss on extinguishment of a note payable of $0.5 million in connection with the ENTADFI® APA Agreement, and the change in fair value of the contingent warrant liability. Other income recorded during the three months ended September 30, 2022, relates to the change in fair value of the contingent warrant liability.

Comparison of the Nine Months Ended September 30, 2023 and 2022

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

	Nine Months Ended September 30, 2023	Nine Months Ended September 30, 2022	$ Change	% Change
Operating costs and expenses				
Selling, general and administrative	$ 8,337,615	$ 7,311,243	$ 1,026,372	14.0%
Research and development	2,148,327	2,924,037	(775,710)	(26.5)%
Impairment of deposit on asset purchase agreement	3,500,000	-	3,500,000	100.0%
Total operating expenses	13,985,942	10,235,280	3,750,662	36.6%
Loss from operations	(13,985,942)	(10,235,280)	(3,750,662)	(36.6)%
Total other income (expense)	(1,072,880)	33,375	(1,106,255)	(3,314.6)%
Net loss	$ (15,058,822)	$ (10,201,905)	$ (4,856,917)	(47.6)%

Selling, General and Administrative Expenses

For the nine months ended September 30, 2023, selling, general and administrative expenses increased by approximately $1.0 million compared to the same period in 2022. The increase was mainly attributable to increased commercialization activities for ENTADFI® of $2.2 million, an increase of $1.1 million in professional fees, a loss on impairment of long-lived assets of $0.3 million, and $0.2 million incurred for the loss on related party receivable. These increases were offset by a decrease in employee compensation of $1.0 million, primarily related to lower stock-based compensation expenses and a decrease in executive bonuses and a decrease in various business activities, such as business advisory services, travel related expenses, and rent expense, totaling $0.2 million. In addition, there was a decrease of $1.3 million related to a loss contingency and a decrease of $0.3 million for a non-recurring termination penalty to a former underwriter, for early termination of the agreement with that underwriter, both of which were incurred in the nine months ended September 30, 2022, with no similar expense in the current period.

Research and Development Expenses

For the nine months ended September 30, 2023, research and development expenses decreased by approximately $0.8 million compared to the same period in 2022. The decrease was primarily due to the Company's decision to deprioritize its vaccine programs during the three months ended September 30, 2023.

Impairment of Deposit on Asset Purchase Agreement

During the nine months ended September 30, 2023, a $3.5 million impairment loss was recorded on the deposit for the WraSer asset purchase agreement.

Other Income (Expense)

Other expense incurred during the nine months ended September 30, 2023, primarily relates to interest expense incurred on new notes payable issued in April 2023 related to the acquisition of ENTADFI®, a loss on extinguishment of a note payable of $0.5 million in connection with the ENTADFI® APA Agreement, and the change in fair value of the contingent warrant liability. Other income recorded during the nine months ended September 30, 2022, relates to the change in fair value of the contingent warrant liability.

Liquidity and Capital Resources

Since inception in October 2018 until April 2023, when we acquired ENTADFI®, we 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 now deprioritized vaccine candidates, organizing and staffing our company, performing business planning, establishing our intellectual property portfolio, and raising capital to support and expand such activities. Since our April 2023 acquisition of ENTADFI®, we have been focusing our efforts on building out our commercial capabilities to launch ENTADFI® in the marketplace. 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 $5.3 million and $15.1 million for the three and nine months ended September 30, 2023, respectively. As of September 30, 2023, we had an accumulated deficit of $34.4 million. We also generated negative operating cash flows of $9.3 million for the nine months ended September 30, 2023.

During June 2023, the Company entered into an asset purchase agreement with WraSer for the acquisition of a significant portion of other assets that requires the Company to pay consideration of $8.5 million and one million shares of common stock, of which $3.5 million was paid upon execution of the agreement, $4.5 million of the remainder and common stock is due at closing, and the remaining $500,000 is due June 13, 2024. On September 26, 2023, and its affiliates filed for relief under chapter 11 of the U.S. Bankruptcy Code in the Bankruptcy Court. On October 4, 2023, the parties agreed to amend the WraSer APA. The amendment, which is subject to court approval, seeks, among other things, to eliminate the $500,000 post-closing payment due June 13, 2024 and stagger the $4.5 million cash payment that the Company would otherwise have to pay at closing to: (i) $2.2 million to be paid at closing, (ii) $2.3 million, to be paid in monthly installments of $150,000 commencing January 2024 (the "Post-Closing Payment") and (iii) 789 shares of Series A Preferred Stock to be paid at closing. On October 6, 2023, we were alerted to certain developments in WraSer's operations relating to WraSer's inability to manufacture the active pharmaceutical ingredient for one of the key WraSer Assets, which development we believe constitutes a Material Adverse Effect (as such term is defined in the WraSer APA) that will prevent us from closing the transaction. On October 20, 2023, we filed a motion for relief from the automatic stay in the Bankruptcy Court so that we can exercise our termination rights under the WraSer APA, as amended. WraSer has advised us that it does not believe that a Material Adverse Event occurred. If the Bankruptcy Court does not grant our motion and requires us to complete the transaction, we will not be able to execute our commercialization strategy for the WraSer Assets because there is no manufacturer for the active pharmaceutical ingredient for Zontivity, the key driver for the WraSer acquisition. Due to the WraSer bankruptcy filing and our status as an unsecured creditor of WraSer, it is also unlikely that we will recover the $3.5 million initial payment made or any costs and resources in connection with services provided by the Company under the WraSer MSA. In addition, if the WraSer APA is terminated, we will not be able to recover any such costs.

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, as further discussed in Note 2 of the condensed financial statements included elsewhere in this Report.

We will require significant amounts of additional capital in the short-term, to continue to fund our continuing operations, satisfy existing and future obligations and liabilities, including the remaining payments due under the Veru APA and other contracts entered into in support of the Company's commercialization plans, in addition to funds needed to 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 for funding the Company's operations include generating product revenue from sales of ENTADFI®, which has not yet been successfully commercialized, a process that will require significant amounts of additional capital to complete. In addition, certain of the commercialization activities 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, and obtaining required licensure is various jurisdictions, 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, which creates significant uncertainty that we will be able to successfully launch ENTADFI®. 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, costs related to acquisitions and potential acquisitions, and selling, general and administrative expenditures. We anticipate that we will continue to incur significant expenses for the foreseeable future as we continue to commercialize ENTADFI® and 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 require significant amounts of additional capital in the short-term, to continue to fund our continuing operations, satisfy existing and future obligations and liabilities, including the remaining payments due under the Veru APA and other contracts entered into in support of the Company's commercialization plans, in addition to funds needed to 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. Until we can generate a sufficient amount of revenue from 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 financing 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 our business activities.

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

- 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® and other products for which we have received or will receive marketing approval;
- 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, require more studies than those that we currently expect or change their requirements regarding the data required to support a marketing application;

- 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 other products for which we may have received or will 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;
- the costs of operating as a public company; and

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

Cash Flows

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

	Nine Months Ended September 30, 2023	Nine Months Ended September 30, 2022
Net cash used in operating activities	$ (9,269,131)	$ (5,875,492)
Net cash used in investing activities	(9,864,613)	(31,488)
Net cash provided by financing activities	1,035,060	33,115,222
Net increase (decrease) in cash	$ (18,098,684)	$ 27,208,242

Cash Flows from Operating Activities

Net cash used in operating activities for the nine months ended September 30, 2023 was approximately $9.3 million, which primarily resulted from a net loss of $15.1 million. This was offset by a net change in our operating assets and liabilities of $0.1 million, an impairment loss of $3.5 million related to the deposit on the WraSer APA, an approximate $0.5 million loss on the extinguishment of a note payable, noncash stock-based compensation of approximately $0.6 million, noncash interest expense of approximately $0.5 million, a $0.3 million loss on impairment of long-lived assets, and the loss on related party receivable of approximately $0.3 million.

Net cash used in operating activities for the nine months ended September 30, 2022 was approximately $5.9 million, which primarily resulted from a net loss of approximately $10.2 million, which was partially offset by noncash stock-based compensation of approximately $1.8 million, and a net change in our operating assets and liabilities of approximately $2.6 million.

Cash Flows from Investing Activities

Net cash used in investing activities for the nine months ended September 30, 2023 was approximately $9.9 million, of which approximately $6.1 million was used for the acquisition of ENTADFI®, $3.5 million was used for the deposit in connection with the potential WraSer APA, which closing is pending at September 30, 2023, and $0.3 million is the net change in the receivable from related parties.

Net cash used in investing activities for the nine months ended September 30, 2022 was approximately $31,000, which resulted from purchases of property and equipment and the net change in the receivable from related parties.

Cash Flows from Financing Activities

Net cash provided by financing activities for the nine months ended September 30, 2023 was approximately $1.0 million, and resulted from net proceeds from the exercise of preferred investment options in connection with the warrant inducement transaction of $2.3 million offset by $1.0 million in principal payments on a note payable, $59,000 in purchases of treasury shares, and $205,000 of payment in deferred offering costs.

Net cash provided by financing activities for the nine months ended September 30, 2022 was approximately $33.1 million, and resulted primarily from the close of our IPO and the April and August Private Placements.

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 condensed 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 September 30, 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, except for the following:

Acquisitions

The Company evaluates acquisitions to first determine whether a set of assets acquired constitutes a business and should be accounted for as a business combination. If the assets acquired are not a business, the transaction is accounted as an asset acquisition in accordance with Accounting Standards Codification ("ASC") 805-50, *Asset Acquisitions* ("ASC 805-50"), which requires the acquiring entity to recognize assets acquired and liabilities assumed based on the cost to the acquiring entity on a relative fair value basis, which includes transaction costs in addition to consideration given. Goodwill is not recognized in an asset acquisition and any excess consideration transferred over the fair value of the net assets acquired is allocated to the identifiable assets based on relative fair values. Contingent consideration payments in asset acquisitions are recognized when the contingency is determined to be probable and reasonably estimable. If the assets acquired are a business, the Company accounts for the transaction as a business combination. Business combinations are accounted for by using the acquisition method of accounting. Under the acquisition method, assets acquired, and liabilities assumed are recorded at their respective fair values. The excess of the fair value of consideration transferred over the fair value of the net assets acquired is recorded as goodwill. Contingent consideration obligations are recorded at their fair values on the acquisition date and remeasured at their fair values each subsequent reporting period until the related contingencies are resolved. The resulting changes in fair values are recorded in earnings.

Impairment of Long-Lived Assets

The Company reviews long-lived assets, including intangible assets with finite useful lives, for impairment whenever events or changes in business circumstances indicate that the carrying amount of the assets may not be fully recoverable (a "triggering event"). Factors that the Company considers in deciding when to perform an impairment review include significant underperformance of the long-lived asset in relation to expectations, significant negative industry or economic trends, and significant changes or planned changes in the use of the assets. If an impairment review is performed to evaluate a long-lived asset for recoverability, the Company compares forecasts of undiscounted cash flows expected to result from the use and eventual disposition of the long-lived asset to its carrying value. An impairment loss would be recognized when estimated undiscounted future cash flows expected to result from the use of an asset are less than its carrying amount. The impairment loss would be based on the excess of the carrying value of the impaired asset over its fair value, determined based on discounted cash flows. During the three and nine months ended September 30, 2023, the Company recorded an impairment loss of approximately $267,000 related to approximately $267,000 of implementation costs incurred under cloud computing hosting arrangements that were capitalized during the period. There were no other impairment losses on long-lived assets.

JOBS Act

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

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

Related Party Transactions

As of September 30, 2023, the Company has a receivable from the Company's former CEO of approximately $522,000, of which the full amount is reserved for as the Company does not anticipate recovery of this amount. During the three months ended September 30, 2023, the Company's Audit Committee completed a review of the Company's expenses due to certain irregularities identified with regards to the related party balance. In September 2023, after the review was completed by the Audit Committee, it was determined that our former CEO and an accounting employee charged certain personal expenses on their corporate credit cards that were not recorded as related party receivables. The aggregate amount of such unauthorized charges ranged from approximately (i) $257,000 to $405,000 for all of 2022, (ii) $86,000 to $122,000 for the quarter ended March 31, 2023, and (iii) $79,000 to $150,000 for the quarter ended June 30, 2023.

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 September 30, 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.

In September 2023, after a review completed by the Audit Committee, it was determined that our former CEO and an accounting employee charged certain personal expenses on their corporate credit cards that were not recorded as related party receivables. The aggregate amount of such unauthorized charges ranged from approximately (i) $257,000 to $405,000 for all of 2022, (ii) $86,000 to $122,000 for the quarter ended March 31, 2023, and (iii) $79,000 to $150,000 for the quarter ended June 30, 2023. These unauthorized charges, in addition to personal charges that were identified as such in previous reporting periods, may have constituted personal loans that are not permissible under Section 402 of the Sarbanes-Oxley Act of 2002. The accounting employee was also the CEO's assistant and had roles in the Company's system of internal control over financial reporting, including controls relating to the Company's corporate credit cards. We determined that this credit card misuse arose from the following control deficiencies, which we have determined to be material weaknesses as of September 30, 2023:

- We did not maintain an effective control environment as there was an inadequate segregation of duties with respect to certain cash disbursements. The processing and the approval for payment of credit card transactions and certain bank wires were being handled by the CEO and an accounting employee, and the accounting employee was responsible for the reconciliation of credit card statements and bank statements. This allowed these individuals to submit unauthorized payments to unauthorized third parties.

- We did not have an effective risk assessment process over the identification of fraud risks surrounding the authorization, identification, approval and reporting of personal expenses charged to the Company's corporate credit cards.

- We did not design and maintain effective monitoring of compliance with established accounting policies and procedures.

The material weaknesses in our control environment, risk assessment and monitoring controls contributed to the following additional material weaknesses in our control activities:

- Our controls over the approval and reporting of expenses paid with the Company's credit cards and certain bank wires were not designed and maintained to achieve the Company's objectives.

In addition to the material weaknesses identified above, we also identified the following material weaknesses in internal control over financial reporting existing as of September 30, 2023:

- We failed to employ a sufficient number of staff to maintain optimal segregation of duties, maintain adequate internal controls surrounding information technology procedures, such as a lack of a written information security policy, maintain adequate controls over the approval and posting of journal entries, 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 but could have resulted in material misstatements of our account balances or disclosures of our annual or interim financial statements that would not be prevented or detected. We have developed a remediation plan for these material weaknesses which is described below in *Remediation of Material Weaknesses*.

Remediation of Material Weaknesses

We are committed to maintaining a strong internal control environment and implementing measures designed to help ensure that the material weaknesses are remediated as soon as possible. We believe we have made progress towards remediation and continue to implement our remediation plan for the material weaknesses, which includes steps to increase dedicated qualified personnel including financial consultants, improve reporting processes, and design and implement new controls. Further, following the credit card misuse discussed above, management has designed and begun to implement the following remediation plan:

- Terminated the accounting employee involved in the misuse and reassigned such employee's roles and responsibilities regarding impacted control activities.

- Implemented a travel, entertainment, and gift policy, which our Board approved on August 31, 2023.

- Implement a formal information security policy.

- Review and update, as necessary, the design and operation of our process level and transaction level controls for cash disbursements, credit card transactions, and journal entries. Implement enhanced approval policies.

We will consider the material weaknesses remediated after the applicable controls operate for a sufficient period of time, and management has concluded, through testing, that the controls are operating effectively.

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

Inherent Limitation on the Effectiveness of Internal Control Processes

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

Changes in Internal Control over Financial Reporting

During the fiscal quarter ended September 30, 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 September 30, 2023, the Company had cash of approximately $7.7 million, a working capital deficit of approximately $8.1 million and an accumulated deficit of approximately $34.4 million.

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 making the remaining payments to Veru, 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 are 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, 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 have entered into an asset purchase agreement with WraSer, which has not yet closed. We believe that a material adverse event has occurred with respect to the WraSer Assets, which may prevent us from closing the transactions contemplated under the WraSer APA.

On June 13, 2023, we entered into the WraSer APA with WraSer to purchase the WraSer Assets. Pursuant to the WraSer APA, we paid $3.5 million in cash to WraSer at signing. Specified conditions must be satisfied or waived to complete the Company's acquisition of the WraSer Assets. These conditions are described in detail in the WraSer APA and include, among other requirements: (i) submission of the FDA transfer documentation to transfer ownership of the acquired product regulatory approvals to the Company, (ii) the delivery to the Company of financial statements of Seller and Parent for the fiscal years ended December 31, 2022 and 2021 audited by a qualified auditor reasonably acceptable to the Company, and (iii) that no Material Adverse Effect (as such term is defined in the APA) has occurred and is continuing uncured. If the conditions are not satisfied or waived, the WraSer acquisition may not occur, or may be delayed and such delay may cause the Company to lose some or all of the intended benefits of the acquisition, as well as loss of time, resources, and funding expended in connection with services provided by the Company under the WraSer MSA.

In October 2023, we were alerted to certain developments in WraSer's operations relating to its ability to manufacture the active pharmaceutical ingredient for one of the key WraSer Assets, which development we believe constitutes a Material Adverse Effect that will prevent us from closing the transaction. On October 20, 2023, we filed a motion for relief from the automatic stay in the Bankruptcy Court so that we can exercise our termination rights under the WraSer APA, as amended. WraSer has advised us that it does not believe that a Material Adverse Event occurred. If the Bankruptcy Court does not grant our motion and requires us to complete the transaction, we will not be able to execute our commercialization strategy for the WraSer Assets because there is no manufacturer for the active pharmaceutical ingredient for Zontivity, the key driver for the WraSer acquisition. Due to the WraSer bankruptcy filing and the Company's status as an unsecured creditor of WraSer, it is unlikely that the Company will recover the $3.5 million initial payment made or any costs and resources in connection with services provided by the Company under the WraSer MSA. If the Company does not complete the purchase of the WraSer Assets and the WraSer APA is terminated, the Company will not be able to recover any such costs. Any claims the Company makes for such payment will be general unsecured claims (see Note 5). If the WraSer APA is terminated, then, due to the WraSer bankruptcy filing and our status as an unsecured creditor of WraSer, it is unlikely that we will recover the $3.5 million initial payment made or any costs and resources in connection with services provided by the Company under the WraSer MSA.

WraSer has recently filed for bankruptcy. If the bankruptcy court requires us to complete the transactions completed by the WraSer APA, we are unlikely to receive previously anticipated benefits from the WraSer APA or recoup any costs already incurred pursuant to the WraSer APA and WraSer MSA.

On September 26, 2023, WraSer and its affiliates filed for relief under chapter 11 of the U.S. Bankruptcy Code in the Bankruptcy Court. On October 4, 2023, the parties agreed to amend the WraSer APA. Shortly after its bankruptcy filing, WraSer filed a motion seeking approval of the WraSer APA as amended. On October 6, 2023, we were alerted to certain developments in WraSer's operations relating to WraSer's inability to manufacture the active pharmaceutical ingredient for one of the key WraSer Assets, which development we believe constitutes a Material Adverse Effect (as such term is defined in the WraSer APA) that will prevent us from closing the transaction. On October 20, 2023, we filed a motion for relief from the automatic stay in the Bankruptcy Court so that we can exercise our termination rights under the WraSer APA, as amended. WraSer has advised us that it does not believe that a Material Adverse Event occurred. If the Bankruptcy Court does not grant our motion and requires us to complete the transaction, we will be obligated to make the remaining payments under the terms of the WraSer APA, and we will not be able to execute our commercialization strategy for the WraSer Assets because there is no manufacturer for the active pharmaceutical ingredient for Zontivity, the key driver for the WraSer acquisition. Due to the WraSer bankruptcy filing and our status as an unsecured creditor of WraSer, it is also unlikely that we will recover the $3.5 million initial payment made or any costs and resources in connection with services provided by the Company under the WraSer MSA.

Company shareholders may not realize a benefit from the ENTADFI® acquisition or, if completed, the WraSer acquisition, commensurate with the ownership dilution they will experience in connection with the transactions.

If the Company is unable to realize the full strategic and financial benefits currently anticipated from the recent ENTADFI acquisition or pending acquisition of the WraSer Assets, our shareholders may experience a dilution of their ownership interests our Company without receiving any commensurate benefit, or only receiving part of the commensurate benefit to the extent the Company is able to realize only part of the strategic and financial benefits currently anticipated from the transactions.

The issuance or conversion of securities could result in significant dilution in the equity interest of existing shareholders and adversely affect the marketplace of the securities.

The issuance or conversion of common shares or other securities convertible into common shares could result in significant dilution in the equity interest of existing shareholders and adversely affect the market price of the common shares. We have issued 3,000 shares of Series A Preferred Stock to Veru which are initially convertible, in the aggregate, into 5,709,935 shares of the Company's common stock, subject to adjustment and certain shareholder approval limitations specified in the Certificate of Designations.

We may have violated Section 13(k) of the Exchange Act (implementing Section 402 of the Sarbanes-Oxley Act of 2002) and may be subject to sanctions as a result.

Section 13(k) of the Exchange Act provides that it is unlawful for a company that has a class of securities registered under Section 12 of the Exchange Act to, directly or indirectly, including through any subsidiary, extend or maintain credit in the form of a personal loan to or for any of its directors or executive officers. In the fiscal year ended December 31, 2022 and the nine months ended September 30, 2023, we paid certain expenses of Joseph Hernandez, our former Chief Executive Officer and Chairman of the Board, which may be deemed to be personal loans made by us to Mr. Hernandez that are not permissible under Section 13(k) of the Exchange Act. Issuers that are found to have violated Section 13(k) of the Exchange Act may be subject to civil sanctions, including injunctive remedies and monetary penalties, as well as criminal sanctions. The imposition of any of such sanctions on us could have a material adverse effect on our business, financial position, results of operations or cash flows.

Misconduct and errors by our current and former employees and our third-party service providers could cause a material adverse effect on our business and reputation.

Our employees and third-party service providers are integral to our business operations, including confidential information. If any such information were leaked to unintended recipients due to human error, theft, malicious sabotage or fraudulent manipulation, we may be subject to liability for loss of such information. Further, if any of our employees or third-party service providers absconded with our proprietary data or know-how in order to compete with us, our competitive position may be materially and adversely affected.

Any improper conduct or use of funds by any of our employees or third-party service providers in contravention of our protocols and policies may lead to regulatory and disciplinary proceedings involving us. We may be perceived to have facilitated or participated in such conduct and we could be subject to liability, damages, penalties and reputational damage. It is impossible to completely identify and eradicate all risks of misconduct or human errors, and our precautionary measures may not be able to effectively detect and prevent such risks from happening.

Occurrence of any of the above risks could result in a material adverse effect on our business and results of operations, as we are exposed to potential liability to borrowers and investors, reputational damage, regulatory intervention, financial harm. Our ability to attract new and retain existing borrowers and investors and operate as an ongoing concern may be impaired.

We may consider strategic alternatives in order to maximize stockholder value, including financing, strategic alliances, licensing arrangements, acquisitions or the possible sale of our business. We may not be able to identify or consummate any suitable strategic alternatives and any consummated strategic alternatives may not be successful.

We may consider all strategic alternatives that may be available to us to maximize stockholder value, including financings, strategic alliances, licensing arrangements, acquisitions or the possible sale of our business. Our exploration of various strategic alternatives may not result in any specific action or transaction. To the extent that this engagement results in a transaction, our business objectives may change depending upon the nature of the transaction. There can be no assurance that we will enter into any transaction as a result of the engagement. Furthermore, if we determine to engage in a strategic transaction, we cannot predict the impact that such strategic transaction might have on our operations or stock price. We also cannot predict the impact on our stock price if we fail to enter into a transaction.

In addition, we face significant competition in seeking appropriate strategic partners, and the negotiation process is time-consuming and complex. Moreover, we may not be successful in our efforts to establish a strategic partnership or other alternative arrangements for our business activities because they may be deemed to be at too early of a stage of development for collaborative effort. Any delays in entering into new strategic partnership agreements harm our business prospects, financial condition and results of operations.

If we license products or businesses, we may not be able to realize the benefit of such transactions if we are unable to successfully integrate them with our existing operations and company culture. We cannot be certain that, following a strategic transaction or license, we will achieve the results, revenue or specific net income that justifies such transaction.

As a result of our failure to timely file our Quarterly Report on Form 10-Q for the quarter ended June 30, 2023, we are currently ineligible to file new short form registration statements on Form S-3, which may impair our ability to raise capital on terms favorable to us, in a timely manner or at all.

Form S-3 permits eligible issuers to conduct registered offerings using a short form registration statement that allows the issuer to incorporate by reference its past and future filings and reports made under the Securities Exchange Act of 1934, as amended, or the Exchange Act. In addition, Form S-3 enables eligible issuers to conduct primary offerings "off the shelf" under Rule 415 of the Securities Act of 1933, as amended, or the Securities Act. The shelf registration process, combined with the ability to forward incorporate information, allows issuers to avoid delays and interruptions in the offering process and to access the capital markets in a more expeditious and efficient manner than raising capital in a standard registered offering pursuant to a Registration Statement on Form S-1.

As a result of our failure to timely file our Quarterly Report on Form 10-Q for quarter ended June 30, 2023, we are currently ineligible to file new short form registration statements on Form S-3 and we will be unable to conduct "off the shelf" offerings under Rule 415 of the Securities Act using our currently effective Registration Statement on Form S-3 (File No. 333-270383) after we file our annual report for the fiscal year ending December 31, 2023. As a result, we may be unable to conduct an "at the market" offering pursuant to our At The Market Offering Agreement with H.C. Wainwright & Co., LLC after December 31, 2023. In addition, if we seek to access the capital markets through a registered offering during the period of time that we are unable to use Form S-3, we may be required to publicly disclose the proposed offering and the material terms thereof before the offering commences, we may experience delays in the offering process due to SEC review of a Form S-1 registration statement and we may incur increased offering and transaction costs and other considerations. Disclosing a public offering prior to the formal commencement of an offering may result in downward pressure on our stock price. In addition, our inability to conduct an offering "off the shelf" may require us to offer terms that may not be advantageous (or may be less advantageous) to us or may generally reduce our ability to raise capital in a registered offering. If we are unable to raise capital through a registered offering, we would be required to conduct our financing transactions on a private placement basis, which may be subject to pricing, size and other limitations imposed under Nasdaq rules.

If we fail to maintain proper and effective internal controls, our ability to produce accurate financial statements on a timely basis could be impaired. We have identified weaknesses in our internal controls, and we cannot provide assurances that these weaknesses will be effectively remediated or that additional material weaknesses will not occur in the future.

We are subject to the reporting requirements of the Exchange Act, the Sarbanes-Oxley Act and Nasdaq rules and regulations. The Sarbanes-Oxley Act requires, among other things, that we maintain effective disclosure controls and procedures and internal control over financial reporting. Effective internal control over financial reporting is necessary for us to provide reliable financial reports and, together with adequate disclosure controls and procedures, is designed to prevent fraud. We must perform system and process evaluation and testing of our internal controls over financial reporting to allow management to report on the effectiveness of our internal controls over financial reporting in our Annual Report on Form 10-K for each year, as required by Section 404 of the Sarbanes-Oxley Act ("Section 404"). This requires significant management efforts and requires us to incur substantial professional fees and internal costs to expand our accounting and finance functions. Any failure to implement required new or improved controls, or difficulties encountered in their implementation, could cause us to fail to meet our reporting obligations. In addition, any testing by us, as and when required, conducted in connection with Section 404, or any subsequent testing by our independent registered public accounting firm, as and when required, may reveal deficiencies in our internal controls over financial reporting that are deemed to be significant deficiencies or material weaknesses or that may require prospective or retroactive changes to our financial statements, or may identify other areas for further attention or improvement. Furthermore, we cannot be certain that our efforts will be sufficient to remediate or prevent future material weaknesses or significant deficiencies from occurring.

We do not yet have effective disclosure controls and procedures, or internal controls over all aspects of our financial reporting. Specifically, we have identified the following control deficiencies which we believe are material weaknesses.

- We did not maintain an effective control environment as there was an inadequate segregation of duties with respect to certain cash disbursements. The processing and the approval for payment of credit card transactions and certain bank wires were being handled by the CEO and an accounting employee, and the accounting employee was responsible for the reconciliation of credit card statements and bank statements. This allowed these individuals to submit unauthorized payments to unauthorized third parties.

- We did not have an effective risk assessment process over the identification of fraud risks surrounding the authorization, identification, approval and reporting of personal expenses charged to the Company's corporate credit cards.

- We did not design and maintain effective monitoring of compliance with established accounting policies and procedures.

- Our controls over the approval and reporting of expenses paid with the Company's credit cards and certain bank wires were not designed and maintained to achieve the Company's objectives.

- We failed to employ a sufficient number of staff to maintain optimal segregation of duties, maintain adequate internal controls surrounding information technology procedures, such as a lack of a written information security policy, maintain adequate controls over the approval and posting of journal entries, 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.

We cannot provide assurances that these weaknesses will be effectively remediated or that additional material weaknesses will not occur in the future.

As a result of the material weaknesses in our internal controls over financial reporting described above, and other matters raised or that may in the future be raised by the SEC, we may face for the prospect of litigation or other disputes which may include, among others, claims invoking the federal and state securities laws, contractual claims or other claims arising from the material weaknesses in our internal control over financial reporting and the preparation of our financial statements, any of which claims could result in adverse effects to our business. As of the date hereof, we have no knowledge of any such litigation or dispute.

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 commercial sale on a timely basis, with sufficient quality, and at commercially reasonable prices, we may be required to delay or suspend commercial sales and/or 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 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®. 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® are 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® are 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® achieves 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®;
- Unforeseen complications arise with respect to use of ENTADFI® or
- sufficient third-party insurance coverage or reimbursement does not remain available.

ENTADFI® is subject to competition from other BPH drugs and larger, well-established companies with substantially greater resources than us.

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 the reach of ENTADFI® 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.

There can be no assurance that we will be able to comply with the continued listing standards of Nasdaq.

Our continued eligibility for listing on Nasdaq depends on our ability to comply with Nasdaq's continued listing requirements.

On September 18, 2023, we received notice from Nasdaq staff indicating that, based upon the closing bid price of the Common Stock for the prior 30 consecutive business days, we were not in compliance with the requirement to maintain a minimum bid price of $1.00 per share for continued listing on Nasdaq, as set forth in Nasdaq Listing Rule 5550(a)(2). We have 180 days from September 18, 2023, or through March 16, 2024, to regain compliance with the Bid Price Rule.

If Nasdaq delists our common stock from trading on its exchange for failure to meet the Bid Price Rule or any other listing standards, we and our stockholders could face significant material adverse consequences including:

- a limited availability of market quotations for our securities;
- a determination that our common stock is a "penny stock," which will require brokers trading in our common stock to adhere to more stringent rules, possibly resulting in a reduced level of trading activity in the secondary trading market for our common stock;

- a limited amount of analyst coverage; and
- a decreased ability to issue additional securities or obtain additional financing in the future.

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, Use of Proceeds, and Issuer Purchase of Equity Securities.

There are no transactions that have not been previously included in a Current Report on Form 8-K.

Issuer Purchases of Equity Securities

There were no share repurchases for the three months ended September 30, 2023.

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 (incorporated by reference to the Registrant's Current Report on Form 8-K filed with the SEC on April 24, 2023).
3.2	Amended and Restated Certificate of Incorporation of the Company (incorporated by reference to the Registrant's Current Report on Form 8-K filed with the SEC on February 24, 2022).
3.3	Third Amended and Restated Bylaws of the Company (incorporated by reference to the Registrant's Current Report on Form 8-K filed with the SEC on June 6, 2023).
4.1	Certificate of Designations of Series A Preferred Stock (incorporated by reference to the Registrant's Current Report on Form 8-K filed with the SEC on October 3, 2023).
10.1	Amendment to Asset Purchase Agreement, dated as of September 29, 2023, by and between Blue Water Biotech, Inc. and Veru Inc. (incorporated by reference to the Registrant's Current Report on Form 8-K filed with the SEC on October 3, 2023).
10.2	Employment Agreement, dated October 4, 2023, between the Company and Dr. Neil Campbell (incorporated by reference to the Registrant's Current Report on Form 8-K filed with the SEC on October 10, 2023).
10.3	Employment Agreement, dated October 4, 2023, between the Company and Bruce Harmon (incorporated by reference to the Registrant's Current Report on Form 8-K filed with the SEC on October 10, 2023).
10.4	Form of Indemnification Agreement (incorporated by reference to the Registrant's Current Report on Form 8-K filed with the SEC on October 10, 2023).
10.5	Form of Amendment, dated October 5, 2023, to Asset Purchase Agreement, dated June 13, 2023, by and among WraSer, LLC, Xspire Pharma, LLC, Legacy-Xspire Holdings, LLC and Blue Water Biotech, Inc. (incorporated by reference to the Registrant's Quarterly Report on Form 10-Q filed with the SEC on October 20, 2023.
10.6* #	Exclusive Distribution Agreement, dated September 20, 2023, between the Company and Cardinal Health 105, LLC
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 portions of this exhibit (indicated by "[***]") have been omitted pursuant to Item 601(b)(10)(iv) of Regulation S-K as we have determined they (1) are not material and (2) are the type that the Company treats as private or confidential. The Registrant hereby agrees to furnish a copy of any omitted portion to the SEC upon request.

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: November 17, 2023

/s/ Dr. Neil Campbell
Dr. Neil Campbell
Chief Executive Officer
(principal executive officer)

Date: November 17, 2023

By: /s/ Bruce Harmon
Bruce Harmon
Chief Financial Officer
(principal financial and accounting officer)

CERTAIN IDENTIFIED INFORMATION HAS BEEN EXCLUDED FROM THIS EXHIBIT BECAUSE IT IS BOTH (I) NOT MATERIAL AND (II) THE TYPE THAT THE COMPANY TREATS AS PRIVATE OR CONFIDENTIAL. THE REDACTED TERMS HAVE BEEN MARKED WITH THREE ASTERISKS [***].

Exclusive Distribution Agreement

This **Exclusive Distribution Agreement** (the "**Agreement**") is made as of September 20, 2023 (the "**Effective Date**"), between Blue Water Biotech, Inc., a Delaware corporation, with an address of 201 East Fifth Street, Suite 1900 Cincinnati, OH, 45202 ("**Client**"), and Cardinal Health 105, LLC, an Ohio limited liability company, with an address of 501 Mason Road, Suite 200, La Vergne, Tennessee, 37086 ("**Cardinal Health**"). Client and Cardinal Health each individually a "**Party**" and collectively the "**Parties**".

RECITALS

a. Client is, among other things, in the business of developing and marketing pharmaceutical products in the United States, its territories, possessions and commonwealths ("**Territory**").

b. Cardinal Health is, among other things, in the business of distributing pharmaceutical products to wholesalers, specialty distributors, physicians, clinics, hospitals, pharmacies, and other health care providers in the Territory, and of providing information systems and other services that support its clients' use of its distribution capabilities.

c. Client desires to engage Cardinal Health as its exclusive third-party logistics distribution agent for commercial sales of Entadfi product in all formulations and any such other product as may be mutually agreed to by the Parties in writing (collectively, "**Product**"), and to perform certain other services described in this Agreement, all upon the terms and conditions set forth in this Agreement.

TERMS

In consideration of the mutual covenants, terms and conditions set forth below, the Parties agree as follows:

1. APPOINTMENT/AUTHORIZATION

1.1. Appointment. Subject to the terms and conditions set forth in this Agreement, during the Term, Client appoints Cardinal Health as its exclusive third-party logistics distribution agent and as an authorized distributor of record of Product in the Territory to Client's customers, including, but not limited to, wholesalers, specialty distributors, physicians, clinics, hospitals, pharmacies, and other health care providers in the Territory (collectively, "**Customers**").

1.2. Acceptance of Appointment. Subject to the terms and conditions set forth in this Agreement, Cardinal Health accepts the appointment to represent Client as its exclusive third- party logistics distribution agent and as an authorized distributor of record of Product to Customers in the Territory in accordance with this Agreement, the OPG (as defined below) and Quality Agreement which sets forth provisions related to the regulatory aspects of the receipt, storage, and distribution of Product (the "**Quality Agreement**"). The Parties agree to finalize and execute a mutually agreeable Quality Agreement prior to the commercial launch of Product. Once mutually agreed, the Quality Agreement is considered attached hereto as **Exhibit C** and incorporated by reference. To the extent that there are any conflicts between this Agreement, the OPG, and/or the Quality Agreement, this Agreement controls, the Quality Agreement controls solely with respect to quality-related matters.

2. SERVICES

2.1. Services. Cardinal Health agrees to provide the services set forth in the Operating Guidelines ("**OPG**"), which include, without limitation, storage, distribution, returns, customer support, financial support, Electronic Data Interchange ("EDI"), and system access support ("Services"). The Parties agree to finalize and execute a mutually agreeable OPG prior to the commercial launch of Product. Once mutually agreed, the OPG is considered attached hereto as **Exhibit A** and incorporated by reference.

2.2. Amendments to Operating Guidelines. Client agrees to provide Cardinal Health with at least ninety (90) days prior written notice of all changes that may require a change, modification, or amendment to the scope of Services set forth in the OPG. No change, modification, or amendment to the OPG is effective unless made by mutual written agreement of the Parties. The foregoing notwithstanding, Client acknowledges and agrees that any change, modification, or amendment to the OPG may result in an increase in the Fees (as defined in Article 5).

2.3. Compliance to Operating Guidelines. Cardinal Health agrees to provide services as set forth in the OPG for up to one hundred twenty-five percent (125%) of Client's Forecast (defined below). If (i) Client's or Client's Customers' shipments of Product to Cardinal Health or (ii) Client's or Client's Customers' Product orders exceed Client's Forecast by more than twenty-five percent (25%), Cardinal Health agrees to use commercially reasonable efforts to meet the requirements of the OPG, provided however, that Client acknowledges that Cardinal Health may not be able to meet all guidelines relating to response and shipping times for any amount exceeding 25% of the Client's Forecast.

2.4. Product Returns. Cardinal Health agrees to process and handle all Product returns in accordance with the OPG; provided however, Client acknowledges that any customization or additional return services requested by Client may result in an additional fee as agreed by the Parties.

2.5. Product Recalls. Client is solely responsible for all Product recalls, provided however that Cardinal Health is responsible for Product recalls to the extent arising from Cardinal Health's gross negligence or willful misconduct, subject to the terms of this Agreement. In the event Product is subject to recall, or Client, on its own initiative, recalls any Product, Cardinal Health agrees to provide assistance to Client as set forth in the OPG and as mutually agreed upon, if Client agrees to pay to Cardinal Health an amount equal to Cardinal Health's actual, reasonable and documented costs incurred with any such recall services. Such cost is in addition to the Fees described in Article 5 below.

2.6. Replacement Products. Notwithstanding any term or condition of this Agreement, the OPG or the Quality Agreement, Client understands, acknowledges, and agrees that Cardinal Health has no obligation hereunder to ship to any Customer any replacement Product that is a controlled substance. As used in this Agreement, the OPG or the Quality Agreement, 'controlled substance' means any drug, substance, or immediate precursor (including listed chemicals) that is listed in schedule I, II, III, IV, or V or designated as a list I or list II chemical pursuant to the federal Controlled Substances Act or similar provisions under state law.

2.7. Drug Samples. Client understands, acknowledges, and agrees that the distribution of drug samples must comply with applicable state and federal laws and regulations. Among other obligations, distribution of drug samples may be initiated only by formal written request containing information about both Client and the practitioner making the request. Only practitioners licensed in their state to prescribe the requested drugs may request drug samples.

3. PRODUCT SUPPLY/CLIENT RESPONSIBILITIES

3.1. Facility. Client agrees to deliver Product to Cardinal Health at Cardinal Health's facility located at 15 Ingram Boulevard, La Vergne, Tennessee 37086 and/or 501 Mason Road, Suite 200, La Vergne, Tennessee 37086, or to such other distribution facility as may be designated by Cardinal Health to Client in writing ("**3PL Facility**").

3.2. Delivery and Title. [***] is responsible for delivery of Product to and from the 3PL Facility, including all costs, expenses and risk of loss associated with such delivery. Title to Product remains with [***] at all times, even when Product is stored or warehoused at the 3PL Facility. [***] agrees to insure the Product at all times for damage, loss, destruction, theft or any such other property damage ("**Loss**") as further set forth in Article 13 below. Except for Loss resulting solely from the gross negligence or willful misconduct of [***], [***] bears all risk of Loss with respect to the Product.

3.3. Forecast and Price List.

a. Forecast. [***] agrees to provide [***] with a forecast of the volume of Product to be handled by [***] under this Agreement, not less often than [***] (the "**Forecast**"). All forecasts, including the Forecast, are used for the express purpose of operational planning. In the event of a significant variance from the Forecast or a change in core business that could reasonably be expected to have a material effect upon the obligations of either Party hereunder, the Party so affected may notify the other Party that it wishes to negotiate an appropriate adjustment to the Fees. The Parties must meet within [***] days of such notification to discuss the merits and implementation of any such adjustment. If the Parties are unable to come to a resolution regarding any such adjustment, the Party originally proposing the adjustment may terminate this Agreement upon [***] days prior written notice to the other Party.

b. Price List. Upon execution of this Agreement, Client agrees to deliver to Cardinal Health a customer list, which sets forth the Product prices (the "**Customer Price List**"). Client agrees to notify Cardinal Health of any change in the Customer Price List not less than three (3) business days prior to the effective date of any such change. Cardinal Health agrees to use commercially reasonably efforts to implement such price change in accordance with Client's instruction.

3.4. Shipment Inspection. Cardinal Health agrees to visually inspect each shipment of Product for external damage or loss in transit and notify Client of any such evident damage or loss as provided in the OPG.

4. INFORMATION SYSTEM ACCESS

4.1. Access. During the Term and subject to the terms herein, Client may use password(s) and identification number(s) provided by Cardinal Health to remotely access Client Data (defined below) maintained on Cardinal Health's web enabled Operating System Base and certain support services associated therewith, as further set forth in the OPG (collectively, the "**System**") provided that such access is used solely by Client's employees or any of its Representatives (defined below) and for Client's own internal business purposes. Client agrees to use that access solely to access Client Data (defined below) and further agrees not to access or attempt to access any other data, systems, or software. Client is responsible for all use of the passwords and identification elements and must ensure that they are used solely to affect the limited access authorized herein. The limited license to access the System granted herein does not include the right to copy, download or otherwise use any software or non-Client data maintained on the System.

4.2. Data. Cardinal Health acknowledges and agrees that Client has and will retain all right, title, interest, and ownership in and to its data on Cardinal Health's system ("**Client Data**"). Client grants Cardinal Health a limited right to use such Client Data in the performance of its Services or as necessary to conduct its own internal business operations. All such Client Data that Cardinal Health or any of its Representatives (defined below) obtains or to which Cardinal Health or Cardinal Health's Representatives is given access pursuant to or in connection with this Agreement is and remains the sole property of Client, and Cardinal Health has no rights or interests (except as expressly provided herein) to or in such Client Data. The destruction of any Client Data as described in this Article 4: (a) is subject to the prior written approval of Client and (b) must be documented by Cardinal Health in an appropriate certification provided to Client upon request. Cardinal Health agrees to return Client Data to Client in an organized, readable format mutually agreed to by the Parties.

4.3. Fees. Cardinal Health agrees to make the System available to Client at the fees set forth in the Fee Schedule. If Cardinal Health agrees to perform any custom enhancements to the System requested by Client, such customization services are billed separately based on an hourly rate set forth in the Fee Schedule (as defined in Article 5) and prior to such performance, Cardinal Health and Client agree to meet in good faith and negotiate any related increase in the periodic Fees hereunder relative to the ongoing support of the customizations.

4.4. Security. During the Term, Cardinal Health agrees to employ reasonable security measures and policies that are no less secure than those utilized to secure its own Confidential Information and that are designed to safeguard the integrity, accessibility, and confidentiality of Client's data resident on the System. Cardinal Health agrees to establish and maintain reasonable disaster and emergency recovery plans designed to minimize disruption from System operation interruptions. If Cardinal Health confirms a security breach of information that resulted in the loss or unauthorized disclosure or modification of Client Data while such data is in Cardinal Health's custody or control ("**Confirmed Security Breach**"), Cardinal Health agrees to provide written notice to Client within seventy-two (72) hours summarizing in reasonable detail the circumstances of the Confirmed Security Breach and Cardinal Health's reasonable assessment of the impact of such Confirmed Security Breach upon Client. In addition, Cardinal Health agrees to: (i) promptly take all commercially reasonable actions to mitigate the effects of the Confirmed Security Breach; (ii) undertake an investigation of such security breach and reasonably cooperate with Client in connection with such investigation, including, without limitation, by preserving and making available all reasonable and relevant records, logs, files, data reporting, and other materials required to comply with applicable law or as otherwise required by Client; and (iii) reasonably cooperate with Client in Client's efforts in seeking injunctive or other equitable relief against any person or persons who have violated or attempted to violate the security of the Client's data. Cardinal Health agrees to notify Client promptly of any corrective action Cardinal Health takes to prevent any future similar unauthorized use, modification, or disclosure. At Client's request, Cardinal Health agrees to provide to Client the Service Organization Control (SOC) 1 report for the systems on which Client Data resides.

4.5. Client Obligations. Client agrees not to reverse engineer, reverse assemble, decompile, create derivative works, modify, or otherwise attempt to derive the source code of any software on the System or copy, download, modify, or create derivative works of such software. Also, Client agrees not to permit access to the System or related documentation to any other person or entity. The System and all parts thereof, in all their tangible and intangible manifestations, all existing or new enhancements, developments, derivative works, and other modifications to the System (or any part thereof), and all related proprietary rights, are and remains the exclusive property of Cardinal Health.

4.6. Disclaimer. **THE SYSTEM, THE SOFTWARE THEREON AND ANY RESULTS OBTAINED THEREFROM ARE PROVIDED ON AN "AS IS" BASIS, WITHOUT WARRANTY OF ANY KIND, WHETHER EXPRESS, IMPLIED, STATUTORY OR OTHERWISE. CARDINAL HEALTH MAKES NO REPRESENTATIONS OR WARRANTIES, AND HEREBY EXPRESSLY DISCLAIMS ALL REPRESENTATIONS AND WARRANTIES, EXPRESS OR IMPLIED, RELATING DIRECTLY OR INDIRECTLY TO THE SYSTEM OR ANY PART THEREOF INCLUDING WITHOUT LIMITATION WARRANTIES OF MERCHANTABILITY, NONINFRINGEMENT AND FITNESS FOR A PARTICULAR PURPOSE. IF THE SOFTWARE IS FOUND TO INFRINGE ANY THIRD PARTY'S INTELLECTUAL PROPERTY RIGHTS, CARDINAL HEALTH AGREES TO, AT ITS EXPENSE AND ITS SOLE OPTION, EITHER (i) REPLACE THE INFRINGING SOFTWARE WITH NONINFRINGING SOFTWARE, OR (ii) SECURE ADDITIONAL RIGHTS NECESSARY TO MAKE THE SOFTWARE NONINFRINGING.**

4.7. System Availability. Cardinal Health agrees to use reasonable efforts to make the System available for access twenty-four (24) hours a day, seven (7) days a week absent scheduled and emergency maintenance periods and as set forth in the OPG.

4.8. Suspension of Access. In the event of a material breach of any term of this Agreement Cardinal Health may revoke or suspend any or all passwords and identification numbers provided to Client hereunder provided Cardinal Health has given prior notice to Client of such breach and Client was afforded the opportunity to cure such breach as set forth in Section 6.2. Notwithstanding the foregoing, in the event of a breach or threatened breach of the security of the System or the unauthorized disclosure of any information relative to the System, Cardinal Health may immediately revoke or suspend any or all passwords and identification numbers provided to Client hereunder for the period of time reasonably necessary for Cardinal Health to resolve the matter, provided that Cardinal Health agrees to otherwise provide access to Client's data to Client during such period of revocation or suspension by promptly responding to Client's request for such data by e-mail or facsimile.

5. PRICING AND PAYMENT TERMS

5.1. Fees. As compensation for the Services, Client agrees to pay to Cardinal Health the fees ("**Fees**") set forth on **Exhibit B** ("**Fee Schedule**") attached hereto and incorporated by reference.

5.2. Invoices. Cardinal Health agrees to issue an electronic invoice to Client for the Services rendered under this Agreement or for any other amounts due monthly. Payment is due within thirty (30) days of the invoice date via electronic funds transfer (EFT) or Automated Clearing House (ACH). Except to the extent an amount is subject to an unresolved dispute made in good faith and in writing during the applicable pay period, if an amount on an invoice is not paid within the applicable pay period set forth above, Cardinal Health may, at its option elect to (i) impose a service charge on the unpaid amount calculated at the rate of 1.5% per month (or the maximum rate permitted by law if such rate is less than 1.5% per month) until such amount is paid in full and/or (ii) suspend any further Services until such invoice is paid in full. In the event of any good faith dispute regarding an invoice, Client agrees to notify Cardinal Health of such dispute during the applicable pay period set forth above, and Client further agrees to pay any undisputed portion of the invoice as provided herein. Client agrees to pay any amounts owed to Cardinal Health within ten (10) days of resolution of such dispute.

5.3. Fee Adjustment.

a. The Fees are firm for [***]. Thereafter, [***] may evaluate the fee schedule and may adjust the Fees by up to [***] not more often than [***].

b. Notwithstanding anything herein to the contrary, if [***], the Parties agree to meet in good faith and negotiate a mutually acceptable adjustment to the Fees. Notwithstanding any other provision of this Agreement, if the parties fail to agree on a Fee adjustment, either party has the right to terminate this Agreement with [***] days' notice without any fees or penalties due to the other party.

5.4. Taxes. Client agrees to pay when due all sales, use, gross receipts, excise and personal property taxes associated with the Product (excluding any personal property tax associated with Cardinal Health's equipment used in connection with the Services), and other taxes now or hereafter imposed as a result of the transactions contemplated by this Agreement, none of which have been included in the fees payable to Cardinal Health under this Agreement; provided that the amounts payable by Client under this Section does not include taxes based on the net income of Cardinal Health.

6. TERM AND TERMINATION

6.1. Term. The initial term of this Agreement begins on the Effective Date and continues for a period of three (3) years following the first shipment of FDA-approved Product to a commercial customer ("**Initial Term**"), unless terminated earlier pursuant to this Agreement. Thereafter, this Agreement automatically renews for additional terms of one (1) year each (each, a "**Renewal Term**," and together with the Initial Term, the "**Term**"), unless written notice of termination is given by either Party at least ninety (90) days prior to the end of the Initial Term or any Renewal Term.

6.2. Termination by Client. Client has the right to terminate this Agreement upon [***] days written notice to Cardinal Health, provided that, [***].

6.3. Immediate Termination. Either Party has the right to immediately terminate this Agreement if:

a. the other Party files a petition in bankruptcy, or enters into an agreement with its creditors, or applies for or consents to the appointment of a receiver or trustee, or makes an assignment for the benefit of creditors, or suffers or permits the entry of any order adjudicating it to be bankrupt or insolvent and such order is not discharged within thirty (30) days; or

b. the other Party materially breaches any of the provisions of this Agreement, and such breach is not cured within thirty (30) days after the giving of written notice; provided, however, that (i) in the case of a breach that cannot be cured within thirty (30) days, the Parties agree to meet within thirty (30) days after the giving of written notice, formulate a mutually agreeable plan to cure such breach within a reasonable period of time; and (ii) in the case of a failure of Client to make payments in accordance with the terms of this Agreement, Cardinal Health may terminate this Agreement if such payment breach is not cured within ten (10) days following Cardinal Health's delivery of a written notice of non-payment to Client. Notwithstanding the foregoing, if Client does not cure a breach within the applicable period specified in subsections (i) or (ii) above, Cardinal Health may, at its sole discretion, suspend Services for so long as such breach remains uncured and such suspension of Services by Cardinal Health does not waive Cardinal Health's right to terminate this Agreement in its entirety due to Client's failure to cure such breach.

6.4. Effect of Termination. Expiration or termination of this Agreement is without prejudice to any rights or obligations that accrued to the benefit of either Party prior to such expiration or termination. Client agrees to pay Cardinal Health for all Services performed up to the date of termination and further agrees to reimburse Cardinal Health for all costs and expenses incurred, and all non-cancelable commitments made, in accordance with the Agreement and in the performance of Services. Upon termination or expiration of this Agreement, Cardinal Health agrees to return all Product to Client or a designee of Client, at Client's sole cost and expense.

7. REGULATORY

7.1. Audits. No more than once per calendar year and upon thirty (30) business days prior written notice to Cardinal Health, Client or its designee has the right during normal business hours (i.e., 8:00 a.m. to 5:00 p.m. local 3PL Facility time, not to exceed a total of eight (8) business hours), to conduct a complete quality audit. If the timing of such audit falls during "quarter-end" or "year-end" then Cardinal Health agrees to use best efforts to accommodate Client's request. Client has the right to conduct for cause audits immediately, if necessary, to ensure Product safety or if otherwise necessary to implement or support a Product recall.

7.2. Compliance with Laws. Each Party agrees to perform its obligations under this Agreement in compliance with all applicable United States laws, rules, regulations, and guidelines.

8. REPRESENTATIONS AND WARRANTIES

8.1. Cardinal Health. Cardinal Health represents and warrants to Client that:

a. Compliance. Unless otherwise agreed to by the Parties, Cardinal Health agrees to perform Services in accordance with this Agreement, the Quality Agreement and the OPG;

b. Personnel. Each of Cardinal Health's employees, agents or personnel assigned to the perform the Services is fully authorized to perform the Services and has the proper skill, training, and experience to perform the Services in a competent, workmanlike and professional manner;

c. Licenses. Cardinal Health has and agrees to maintain, or will obtain and maintain all necessary approvals, licenses, consents, permits or authorizations of any person or entity (including any governmental authority) (collectively "Approvals") to perform the Services, provided however, if Client requires Services for which Cardinal Health is required to obtain additional Approvals, then Client may be required to pay additional fees for such Services relating to the additional Approvals. Any such additional fees will be as set forth in the Fee Schedule.

8.2. Client. Client represents, warrants, and covenants to Cardinal Health that:

a. Product. The Product is not adulterated or misbranded as provided in the Food, Drug and Cosmetic Act, as amended from time to time;

b. Promotion. Client's activities relating to the promotion, sale and distribution of the Product comply with all applicable laws, rules, regulations, and guidelines;

c. Title and No Infringement. It has all necessary authority and right, title and interest in and to any intellectual property related to the Product for Cardinal Health to perform its obligations herein and the Product does not infringe any patent, trade secret, copyright, trademark, or other proprietary rights of any third party;

d. Safe Handling Instructions. It has provided all safe handling instruction, health and environmental information and material safety data sheets applicable to the Product or to any materials supplied by Client in writing in sufficient time for review and training by Cardinal Health prior to delivery.

8.3. Mutual. Each Party represents and warrants to the other Party that:

a. Existence and Power. Such Party (i) is duly organized, validly existing and in good standing under the laws of the state in which it is organized, (ii) has the power and authority and the legal right to own and operate its property and assets, and to carry on its business as it is now being conducted, and (iii) is in compliance with all requirements of applicable laws, except to the extent that any noncompliance would not materially adversely affect such Party's ability to perform its obligations under the Agreement;

b. Authorization and Enforcement of Obligations. Such Party (i) has the power and authority and the legal right to enter into this Agreement and to perform its obligations hereunder and (ii) has taken all necessary action on its part to authorize the execution and delivery of this Agreement and the performance of its obligations hereunder;

c. Execution and Delivery. This Agreement has been duly executed and delivered on behalf of such Party, and constitutes a legal, valid, binding obligation, enforceable against such Party in accordance with its terms;

d. No Consents. All necessary consents, approvals and authorizations of all regulatory authorities and other persons required to be obtained by such Party in connection with the Agreement have been obtained; and

e. No Conflict. The execution and delivery of this Agreement and the performance of such Party's obligations hereunder (i) do not conflict with or violate any requirement of applicable laws; and (ii) do not materially conflict with or constitute a material default or require any consent under, any contractual obligation of such Party.

f. Debarment. In accordance with the provisions of 48 C.F.R. § 52.209-6, each Party represents, warrants and certifies that neither it nor its principals was or is debarred, suspended, proposed for debarment or otherwise determined to be ineligible to participate in federal health care programs (as that term is defined in 42 U.S.C. 1320a-7b(f)) or convicted of a criminal offense related to the provision of health care items or services, but has not yet been debarred, suspended, proposed for debarment or otherwise determined to be ineligible to participate in federal health care programs. In the event that a Party, or any of its principals, is debarred, suspended, proposed for debarment or otherwise determined to be ineligible to participate in federal health care programs or convicted of a criminal offense related to the provision of health care items or services, such Party will promptly notify the other Party and such Party may terminate this Agreement immediately upon the effective date of any such debarment, suspension, proposal for debarment or other determination of ineligibility.

8.4. Limitations. THE REPRESENTATIONS AND WARRANTIES SET FORTH IN THIS ARTICLE 8 ARE THE SOLE AND EXCLUSIVE REPRESENTATIONS AND WARRANTIES MADE BY EACH PARTY TO THE OTHER AND NEITHER PARTY MAKES ANY OTHER REPRESENTATIONS, WARRANTIES OR GUARANTEES OF ANY KIND WHATSOEVER, INCLUDING WITHOUT LIMITATION ANY IMPLIED WARRANTIES OF MERCHANTABILITY, NON-INFRINGEMENT OR FITNESS FOR A PARTICULAR PURPOSE.

9. TRADEMARKS

9.1. Neither Party has the right to use the name of the other Party or any Affiliate of the other Party, or the other Party's or such Affiliates' trademarks, service marks, logos, or other similar marks in any manner except with the prior written approval of that Party, provided that the foregoing does not prohibit Cardinal Health's use of Client's names or marks in connection with the performance of the Services in a manner consistent with this Agreement. "**Affiliate**," as used in this Agreement, means any legal entity which, during the Term hereof, controls, is controlled by, or is under common control with, such Party. For purposes of this definition, an entity is deemed to control another entity if it owns or controls, directly or indirectly, at least fifty percent (50%) of the voting interest of all equity interests of the other entity (or other such comparable ownership interest for an entity other than a corporation).

10. CONFIDENTIALITY AND NON-USE

10.1. Mutual Obligation. While performing their respective obligations under this Agreement, one Party (the "Discloser") may disclose to the other Party (the "Recipient") certain Confidential Information (defined below). The Recipient is not permitted to use the other Party's Confidential Information (defined below) except as necessary for Recipient to perform its obligations under this Agreement. The Recipient is not permitted to disclose the Discloser's Confidential Information to any third party without the prior written consent of the Discloser. Notwithstanding the foregoing, the Recipient may disclose the Discloser's Confidential Information to the extent required by law, regulation or court or administrative order, if the Recipient gives the Discloser as much prior notice of the requirement for and contents of such disclosure as is practicable under the circumstances. Notwithstanding the foregoing, the Recipient may disclose the Discloser's Confidential Information to any of Recipient's Affiliates (defined below) or Representatives that need to know such Confidential Information for the purpose of performing under this Agreement. Prior to such Affiliate or Representative receiving the Discloser's Confidential Information, (A) Recipient must advise the Affiliate or Representative of the contents of this article, and (B) such Affiliate or Representative must agree to be bound by the terms of this article or agree to be bound by confidentiality and use obligations no less restrictive than those set forth in this article. The Recipient agrees to use all reasonable safeguards to prevent unauthorized use by such Affiliates and Representatives and further agrees to immediately notify the Discloser upon becoming aware of any breach of the confidentiality obligations of this Article 10. "**Representatives**" as that term is used herein means the employees, officers, directors, agents, consultants, or other authorized representatives of the Party.

10.2. Definition. As used in this Agreement, the term "**Confidential Information**" means all confidential or proprietary information furnished by Discloser, or any of its Representatives or Affiliates, to the Recipient or its Representatives or Affiliates in connection with the services or performance of this Agreement, whether furnished before, on or after the date of this Agreement and furnished in any form, including but not limited to written, verbal, visual, electronic or in any other media or manner. Confidential Information includes all proprietary technologies, know-how, trade secrets, discoveries, inventions, and any other intellectual property (whether or not patented), analyses, compilations, business or technical information and other materials prepared by either Party, or any of their respective Representatives, containing or based in whole or in part on any such information furnished by the other Party or its Representatives. The existence of this Agreement and the terms of this Agreement are Confidential Information of each Party.

10.3. Exclusions. Notwithstanding anything herein to the contrary, Confidential Information does not include information that (A) is or becomes generally available to the public other than as a result of a breach of this Agreement, or (B) is already known by the receiving Party at the time of disclosure as evidenced by the receiving Party's written records, or (C) becomes available to the receiving Party on a non-confidential basis from a source that is entitled to disclose it on a non-confidential basis, or (D) was or is independently developed by or for the receiving Party without reference to the Confidential Information, as evidenced by the receiving Party's written records.

10.4. No Implied License. The receiving Party obtains no right of any kind or license under any patent application or patent by reason of this Agreement. All Confidential Information remains the sole property of the Party disclosing such information or data.

10.5. Return of Confidential Information. Upon termination of this Agreement, the Recipient agrees to, upon request, promptly return within thirty (30) days all Confidential Information, including any copies thereof, and cease its use or, at the request of the Discloser, Recipient agrees to promptly destroy the same and certify such destruction to the disclosing Party; except for a single copy thereof, which may be retained for the sole purpose of determining the scope of the obligations incurred under this Agreement. Notwithstanding the foregoing, neither Party is required to destroy any back-up tapes, archival systems, or similar inactive databases so long as such tapes, systems or databases are not readily accessible and are routinely deleted or overwritten pursuant to an established record retention program, and such destruction does not require a Party to erase or delete information using special programs or techniques.

10.6. Survival. The Parties intend for this Article to supersede that certain Confidentiality Agreement between the parties dated May 4, 2023. The obligations of this Article terminates five (5) years from the expiration of this Agreement.

11. INDEMNIFICATION

11.1. Indemnification by Cardinal Health. Cardinal Health agrees to indemnify and defend Client, its Affiliates, and their respective directors, officers, employees and agents ("**Client Indemnitees**") from and against any and all losses, demands, liabilities, damages, costs and expenses (including reasonable attorney' fees) in connection with any claim, suit, demand, action, investigation or proceeding by any third party ("**Liabilities**") to the extent arising out of or resulting from [***].

11.2. Indemnification by Client. Client agrees to indemnify and defend Cardinal Health, its Affiliates, and their respective directors, officers, employees and agents ("**Cardinal Health Indemnitees**") from and against all Liabilities to the extent arising out of or resulting from [***].

11.3. Indemnification Procedures. All indemnification obligations in this Agreement are conditioned upon the Party seeking indemnification ("**Indemnitee**"): [***].

12. LIMITATIONS OF LIABILITY

12.1. THE MAXIMUM AMOUNT OF [***] TOTAL LIABILITY UNDER THIS AGREEMENT, WHETHER IN CONTRACT OR TORT, INCLUDING, WITHOUT LIMITATION, ANY OF [***] INDEMNITY OR OTHER FINANCIAL OBLIGATIONS UNDER ARTICLE 11, IS [***].

12.2. NEITHER PARTY IS LIABLE TO THE OTHER PARTY FOR [***].

12.3. NOTWITHSTANDING ANYTHING TO THE CONTRARY HEREIN, THE LIMITATIONS IN THIS ARTICLE 12 DO NOT LIMIT CLIENT'S LIABILITY OR RESPONSIBILITY RELATING TO A BREACH OF ITS OBLIGATIONS UNDER ARTICLE 4 HEREIN.

13. INSURANCE

13.1. Insurance Policies. [***]

a. Products and Completed Operations Liability Insurance covering the Products included in this Agreement with a limit of not less than ten million dollars ($10,000,000 USD) per occurrence;

b. All-Risk Property Insurance, including transit coverage, in an amount equal to full replacement value covering Client's property while it is at the 3PL Facility or in transit to or from the 3PL Facility. Client's all- risk property insurance applies to all losses and is primary (with respect both to any insurance issued to Cardinal Health and to any deductible amount or self-insured amount retained by Cardinal Health) except for losses resulting solely from the gross negligence or willful misconduct of Cardinal Health.

c. If any of the required policies of insurance are written on a claims-made basis, then Client agrees to maintain such policies during the entire Term and for a period of not less than five (5) years following the termination or expiration of this Agreement.

13.2. Waiver. Client agrees to obtain a waiver from any insurance carrier with whom Client carries Property Insurance releasing its subrogation rights against Cardinal Health except for losses resulting solely from the gross negligence or willful misconduct of Cardinal Health. Client agrees not to seek reimbursement for any property claim, or portion thereof that is not fully recovered from Client's property insurance except for losses resulting solely from the gross negligence or willful misconduct of Cardinal Health.

13.3. Additional Insured Status. Client agrees to name Cardinal Health, Inc., and its Affiliates as additional insureds under the Products and Completed Operations Liability insurance policies as respects the Products and completed operations outlined in this Agreement. Client agrees that such insurance is primary (with respect both to any insurance issued to Cardinal Health and to any self-insured amount retained by Cardinal Health) regarding Cardinal Health's liability for damage arising out of those products for which they have been added as additional insureds. Such additional insurance status continues during the Term and, if the policies are written on a claims-made basis, continues for not less than five (5) years following termination or expiration of this Agreement.

13.4. Certificates. Client agrees to furnish certificates of insurance to Cardinal Health evidencing the required insurance and additional insured status as soon as practicable after the Effective Date and within thirty (30) days after renewal of such policies. Client agrees to endeavor to provide thirty (30) days written notice of any cancellation prior to the policy(ies) expiration date(s). Client agrees to obtain each insurance policy that is required under this article from an insurance carrier with an A.M. Best rating of at least A-VII.

14. NOTICES

14.1. All notices and other communications hereunder must be made in writing and are deemed given: (A) when delivered personally; (B) when delivered by facsimile transmission (receipt verified); (C) when received or refused, if mailed by registered or certified mail (return receipt requested), postage prepaid; or (D) when delivered if sent by express courier service, to the Parties at the following addresses (or at such other address for a Party as specified by like notice; provided, that notices of a change of address are effective only upon receipt thereof):

Cardinal Health:	Cardinal Health 105, LLC Third-Party Logistics Services 501 Mason Road, Suite 200 La Vergne, TN 37086 Attn: VP, Operations	Client:	Blue Water Biotech, Inc. Cincinnati, OH, 45202 201 East Fifth Street Suite 1900 Cincinnati, OH, 45202 Attn: Erin Henderson
With copy to:	Cardinal Health 105, LLC Third-Party Logistics Services 7000 Cardinal Place Dublin, OH 43017 Attn: Assistant General Counsel		

15. MISCELLANEOUS

15.1. Entire Agreement; Amendments. This Agreement, the attachments and any amendments thereto constitute the entire understanding between the Parties and supersede any contracts, agreements or understanding (oral or written) of the Parties with respect to the subject matter hereof. No term of this Agreement may be amended except upon written agreement of both Parties, unless otherwise provided in this Agreement.

15.2. Captions. The captions in this Agreement are for convenience only and are not to be interpreted or construed as a substantive part of this Agreement.

15.3. Further Assurances. The Parties agree to execute, acknowledge, and deliver such further instruments and to take all such other incidental acts as may be reasonably necessary or appropriate to carry out the purpose and intent of this Agreement.

15.4. No Waiver. Failure by either Party to insist upon strict compliance with any term of this Agreement in any one or more instances are not deemed to be a waiver of its rights to insist upon such strict compliance with respect to any subsequent failure.

15.5. Severability. If any term of this Agreement is declared invalid or unenforceable by a court or other body of competent jurisdiction, the remaining terms of this Agreement continue in full force and effect.

15.6. Independent Contractors. The relationship of the Parties is that of independent contractors, and neither Party is permitted to incur any debts or make any commitments for the other Party except to the extent expressly provided in this Agreement. Nothing in this Agreement is intended to create or should be construed as creating between the Parties the relationship of joint venturers, co-partners, employer/employee or principal and agent.

15.7. Subcontractors. Cardinal Health may not subcontract all or any portion of the Services without the prior written consent of Client. For purposes of clarity, shipping services provided by common transportation carriers (including Cardinal Health's Exclusive Pharmaceutical Transportation Network or EPTN), Product destruction services provided by a third-party vendor, and services related to facility maintenance or security are not considered to be contracted services as related to this Agreement and therefore the businesses performing such services are not considered subcontractors. It is expressly understood that Cardinal Health is not responsible for the performance of shipping services by common carriers for or on behalf of Client.

15.8. Successors and Assigns. This Agreement is binding upon and inures to the benefit of the Parties, their successors and permitted assigns. Except for a Permitted Assignment (defined below), neither Party may assign this Agreement, voluntarily or involuntarily, whether by operation of law or any other manner, without the prior written consent of the other Party, which such consent should not be unreasonably withheld. For the avoidance of doubt, an assignment for purposes of this Section includes a "Change-of-Control Transaction" which means, with respect to either Party, a transaction or a series of related transactions resulting in the sale or transfer of a controlling interest of stock or other equity interests of that Party, a merger of that Party into another entity, a sale of all or substantially all of the assets of that Party or of that Party's line of business to which this Agreement relates, or a transfer of a controlling interest in that Party by operation of law or otherwise. A "Permitted Assignment" means an assignment to an Eligible Affiliate of the assigning party so long as the assigning party provides written notice to the other Party. For purposes of this Section, an "Eligible Affiliate" means an Affiliate whose relationship as such to the assigning party is not the consequence of a Change-of-Control Transaction.

15.9. No Third-Party Beneficiaries. Except as otherwise provided herein, this Agreement is intended to be solely for the benefit of the Parties hereto and is not intended to confer any benefits upon, or create any rights in favor of, any other person.

15.10. Governing Law. This Agreement is governed by and construed under the laws of the State of Delaware, excluding its conflicts of law provisions. **The United Nations Convention on Contracts for the International Sale of Goods does not apply to this Agreement.**

15.11. Dispute Resolution. If any dispute, controversy, or disagreement arises between the Parties ("**Dispute**"), the Parties agree to present such Dispute to the respective presidents or senior executives of Cardinal Health and Client for their consideration and resolution. If such Parties cannot reach a resolution of the Dispute within sixty (60) days, either Party may submit the Dispute to a court of appropriate jurisdiction.

15.12. Prevailing Party. In any dispute resolution proceeding between the Parties in connection with this Agreement, the prevailing Party is entitled to its reasonable attorney's fees and costs in such proceeding.

15.13. Counterparts. This Agreement may be executed in one or more counterparts, each of which is deemed an original but all of which together constitute one and the same instrument. Any photocopy, facsimile or electronic reproduction of the executed Agreement constitutes an original.

15.14. Publicity. Neither Party is permitted to make any press release or other public disclosure regarding this Agreement or the transactions contemplated hereby without the other Party's express prior written consent, except as required under applicable law or by any governmental agency, in which case the Party required to make the press release or public disclosure agrees to use commercially reasonable efforts to obtain the approval of the other Party as to the form, nature and extent of the press release or public disclosure prior to issuing the press release or making the public disclosure.

15.15. Setoff. Without limiting [***] rights under law or in equity, [***], collectively or individually, may exercise a right of set-off against any and all amounts due to [***] from [***] that are [***]. For purposes of this Section, [***].

15.16. Survival. The rights and obligations of the Parties continue under Articles 10 (Confidentiality and Non- Use), to the extent expressly stated therein, 11 (Indemnification), 12 (Limitations of Liability), 13 (Insurance), to the extent expressly stated therein, 14 (Notice) and 15 (Miscellaneous) and Section 6.4 (Effect of Termination), notwithstanding expiration or termination of this Agreement.

15.17. Change in Law. In the event that any applicable federal, state or local law, rule, regulation, policy, or any interpretation thereof, during the Term, is modified, implemented, threatened to be implemented, or determined to prohibit, substantially restrict or in any way materially affect this Agreement or either Party's performance under the terms of this Agreement (each of the foregoing being hereinafter referred to as a "**Change**"), then the Parties agree to promptly negotiate an amendment to this Agreement to preserve the expectations of the Parties to the greatest extent possible in a manner consistent with any such Change.

15.18. Force Majeure. Neither Party is liable in damages for or is considered in breach of this Agreement due to any delay or default in such Party's performance hereunder if such default or delay is caused by events beyond such Party's reasonable control including, but not limited to, acts of God, regulation or law or other action or failure to act of any government or agency thereof, war or insurrection, civil commotion, destruction of production facilities or materials by earthquake, fire, flood or storm, labor disturbances, epidemic, or failure of suppliers, public utilities or common carriers; provided however, that the Party seeking relief hereunder is required to immediately notify the other Party of such cause(s) beyond such Party's reasonable control. Notwithstanding the foregoing, either Party's obligations to pay undisputed money owed or incurred under this Agreement will not be suspended unless the force majeure event prevents the Party responsible for such payment from making such payment by any reasonable means (e.g., the force majeure event has caused the banking and/or mail systems to fail). The Party that may invoke this section is required to use all reasonable endeavors to reinstate its ongoing obligations to the other. If the cause(s) continues unabated for one hundred eighty (180) days, then both Parties agree to meet to discuss modifications to this Agreement that should result from such force majeure event.

[This space left intentionally blank. Signatures appear on following page.]

IN WITNESS WHEREOF, the undersigned have caused their duly authorized representative to execute this Agreement effective as of the date first written above.

CARDINAL HEALTH 105, LLC	**Blue Water Biotech, Inc.**
/s/Joel Wayment	/s/ Erin Henderson
Signature	**Signature**
Joel Wayment	Erin Henderson
Printed Name	**Printed Name**
VP, Operations	Chief Business Officer
Title	**Title**
Sep 21, 2023	Sep 21, 2023
Date	**Date**

[Signature Page to Exclusive Distribution Agreement]

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, Dr. Neil Campbell, 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: November 17, 2023

By: /s/ Dr. Neil Campbell
Dr. Neil Campbell
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, Bruce Harmon, 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: November 17, 2023

By: /s/ Bruce Harmon
Bruce Harmon
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 September 30, 2023, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Dr. Neil Campbell, 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: November 17, 2023

By: /s/ Dr. Neil Campbell
Dr. Neil Campbell
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 September 30, 2023, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Bruce Harmon, 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: November 17, 2023

By: /s/ Bruce Harmon
Bruce Harmon
Chief Financial Officer
(Principal Financial Officer)