**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 June 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 October 20, 2023, the registrant had 17,988,058 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;
- our ability to consummate an acquisition of assets from WraSer;
- 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**

| | June 30, 2023 (Unaudited) | December 31, 2022 |
|---|---|---|
| **ASSETS** | | |
| Current assets | | |
| Cash | $ 9,222,647 | $ 25,752,659 |
| Inventories | 1,171,900 | — |
| Prepaid expenses and other current assets | 685,413 | 469,232 |
| Receivable from related parties, net | 325,052 | 35,850 |
| Total current assets | 11,405,012 | 26,257,741 |
| Prepaid expenses, long-term | 55,499 | 38,617 |
| Property and equipment, net | 14,120 | 14,089 |
| Deferred offering costs | 366,113 | — |
| Intangible asset | 17,906,771 | — |
| **Total assets** | **$ 29,747,515** | **$ 26,310,447** |
| **LIABILITIES AND STOCKHOLDERS' EQUITY** | | |
| Current liabilities | | |
| Accounts payable | $ 2,076,706 | $ 1,499,296 |
| Accrued expenses | 1,419,809 | 2,409,128 |
| Notes payable, net of debt discount of $376,487 | 8,623,513 | — |
| Contingent warrant liability | 14,080 | 14,021 |
| Total current liabilities | 12,134,108 | 3,922,445 |
| Note payable, net of current maturities and debt discount of $462,518 | 4,537,482 | — |
| **Total liabilities** | **16,671,590** | **3,922,445** |
| Commitments and Contingencies (see Note 9) | | |
| **Stockholders' equity** | | |
| Preferred stock, $0.00001 par value, 10,000,000 shares authorized at June 30, 2023 and December 31, 2022; 0 shares issued and outstanding at June 30, 2023 and December 31, 2022 | — | — |
| Common stock, $0.00001 par value, 250,000,000 shares authorized at June 30, 2023 and December 31, 2022; 16,930,457 and 15,724,957 shares issued at June 30, 2023 and December 31, 2022, respectively; 16,413,058 and 15,265,228 shares outstanding at June 30, 2023 and December 31, 2022, respectively | 169 | 157 |
| Additional paid-in-capital | 42,789,961 | 42,331,155 |
| Treasury stock, at cost; 517,399 and 459,729 shares of common stock at June 30, 2023 and December 31, 2022, respectively | (625,791) | (566,810) |
| Accumulated deficit | (29,088,414) | (19,376,500) |
| Total stockholders' equity | 13,075,925 | 22,388,002 |
| **Total liabilities and stockholders' equity** | **$ 29,747,515** | **$ 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 June 30, 2023 | Three Months Ended June 30, 2022 | Six Months Ended June 30, 2023 | Six Months Ended June 30, 2022 |
|---|---|---|---|---|
| Operating expenses | | | | |
| Selling, general and administrative | $ 2,302,747 | $ 3,001,418 | $ 4,068,770 | $ 4,616,987 |
| Research and development | 846,853 | 1,293,467 | 1,929,089 | 1,748,559 |
| Impairment of deposit on asset purchase agreement | 3,500,000 | — | 3,500,000 | — |
| Total operating expenses | 6,649,600 | 4,294,885 | 9,497,859 | 6,365,546 |
| Loss from operations | (6,649,600) | (4,294,885) | (9,497,859) | (6,365,546) |
| Other income (expense) | | | | |
| Interest expense | (213,996) | — | (213,996) | — |
| Change in fair value of contingent warrant liability | (1,674) | 30,303 | (59) | 30,303 |
| Total other income (expense) | (215,670) | 30,303 | (214,055) | 30,303 |
| **Net loss** | **$ (6,865,270)** | **$ (4,264,582)** | **$ (9,711,914)** | **$ (6,335,243)** |
| Cumulative preferred stock dividends | — | — | — | 96,359 |
| Net loss applicable to common stockholders | $ (6,865,270) | $ (4,264,582) | $ (9,711,914) | $ (6,431,602) |
| | | | | |
| Net loss per share attributable to common stockholders, basic and diluted | $ (0.43) | $ (0.36) | $ (0.61) | $ (0.70) |
| Weighted average number of common shares outstanding, basic and diluted | 15,906,725 | 11,995,832 | 15,908,560 | 9,226,621 |

*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** |

| | 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** |

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

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

| | Six Months Ended June 30, 2023 | Six Months Ended June 30, 2022 |
|---|---|---|
| **Cash flows from operating activities** | | |
| Net loss | $ (9,711,914) | $ (6,335,243) |
| 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 | 458,359 | 1,466,459 |
| Amortization of debt discount | 213,996 | — |
| Loss on related party receivable | 165,355 | — |
| Depreciation expense | 3,269 | 3,061 |
| Change in fair value of contingent warrant liability | 59 | (30,303) |
| Changes in assets and liabilities: | | |
| Inventories | (51,900) | — |
| Prepaid expenses and other current assets | (227,201) | (778,453) |
| Prepaid expenses, long-term | (16,882) | (73,974) |
| Deposit | — | (27,588) |
| Accounts payable | 427,409 | 491,760 |
| Accrued expenses | (989,319) | 1,223,613 |
| Net cash used in operating activities | (6,228,769) | (4,060,668) |
| | | |
| **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) | — |
| Net advances to related parties | (454,557) | (7,840) |
| Purchase of property and equipment | (3,300) | (9,339) |
| Net cash used in investing activities | (10,037,628) | (17,179) |
| | | |
| **Cash flows from financing activities** | | |
| Purchase of treasury shares | (58,981) | — |
| Payment of deferred offering costs | (205,093) | (51,304) |
| Proceeds from exercise of stock options | 459 | — |
| 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 placement, net of placement agent discount | — | 7,319,462 |
| Payment of private placement issuance costs | — | (349,630) |
| Net cash provided by (used in) financing activities | (263,615) | 24,391,556 |
| Net increase (decrease) in cash | (16,530,012) | 20,313,709 |
| Cash, beginning of period | 25,752,659 | 1,928,474 |
| Cash, end of period | $ 9,222,647 | $ 22,242,183 |
| | | |
| **Noncash investing and financing activities:** | | |
| Inventory and intangible assets acquired through issuance of notes payable | $ 12,947,000 | $ — |
| Deferred offering costs included in accounts payable and accrued expenses | $ 150,000 | $ 187,500 |
| Deferred offering costs previously included in prepaid expenses | $ (11,020) | $ — |
| Exercise of pre-funded warrants | $ 7 | $ 6 |
| Issuance of restricted stock | $ 5 | $ — |
| Conversion of convertible preferred stock to common stock upon initial public offering | $ — | $ 45 |
| Private placement offering costs included in accounts payable | $ — | $ 75,828 |
| Recognition of contingent warrant liability upon issuance of common stock in private placement | $ — | $ 35,676 |
| Payment of accrued bonus through related party receivable | $ — | $ 140,000 |

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

**BLUE WATER BIOTECH, INC.**
**Notes to Condensed Financial Statements**
**(Unaudited)**

## Note 1 — Organization and Basis of Presentation

### *Organization and Nature of Operations*

Blue Water Biotech, Inc. (formerly 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. The Company holds exclusive, global rights to novel technology licensed from renowned research institutions around the world, including St. Jude, the University of Oxford, CHMC, and UT Health. All of the Company's vaccine candidates are in the pre-clinical developmental stage.

In addition, in April 2023, the Company acquired ENTADFI®, with plans to commercialize it. ENTADFI® is 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 paused its efforts on vaccine development activities to pursue and focus on commercialization activities for ENTADFI®.

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 June 30, 2023, and the condensed statements of operations and the condensed statements of changes in stockholders' equity for the three and six months ended June 30, 2023 and 2022, and the condensed statements of cash flows for the six months ended June 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 June 30, 2023 and its results of operations for the three and six months ended June 30, 2023 and 2022, and its cash flows for the six months ended June 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 six-month periods are also unaudited. Operating results for the three and six months ended June 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 and engaging in research and development activities. The Company's product candidates currently under development will require significant additional research and development efforts prior to commercialization. The Company has financed its operations since inception primarily using proceeds received from seed investors, and proceeds received from its IPO and private placement issuances in April and August 2022 (the "Private Placements", see Note 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.

The Company has incurred substantial operating losses since inception and expects to continue to incur significant operating losses for the foreseeable future. As of June 30, 2023, the Company had cash of approximately $9.2 million, a working capital deficit of approximately $0.7 million and an accumulated deficit of approximately $29.1 million. During April 2023, the Company completed an acquisition of assets that requires the Company to pay initial consideration of $20.0 million, of which $6.0 million was paid upon close and $9.0 million of the remainder was originally due to the seller of the assets within one year of the date these condensed financial statements were issued. The remaining $5.0 million is due in September 2024. On September 29, 2023, the Company entered into an amendment to this agreement (the "Veru APA Amendment"). Pursuant to the Veru APA Amendment, 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 the assets of $1 million on September 29, 2023, and (2) the issuance to the seller of the assets by October 3, 2023, of 3,000 shares of Series A Convertible Preferred Stock of the Company. The Company made such $1 million payment on September 29, 2023 and issued the Series A Preferred Stock on October 3, 2023. (See Notes 5 and 15.) During June 2023, the Company also executed an asset purchase agreement, whereby the Company transferred $3.5 million of cash consideration for the acquisition of a business, for which closing is contingent on certain conditions. The Company will be required to transfer $4.5 million in additional cash consideration if the transaction closes. However, on September 26, 2023, WraSer filed for bankruptcy under Chapter 11 of the U.S. Bankruptcy Code, 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. These circumstances create substantial uncertainty, should the acquisition not close, that the Company will be able to recover the initial $3.5 million payment, and therefore the Company wrote off the balance of the advance payment as of June 30, 2023 (see Notes 5 and 15).

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 above 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 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, obtaining required licensure in various jurisdictions, and building a salesforce, as well as attempting to secure additional required funding through equity or debt financings if available; however, there are currently no commitments in place for further financing nor is there any assurance that such financing will be available to the Company on favorable terms, if at all, 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 curtail any clinical trials, development and/or commercialization of products and product candidates, and it may take additional measures to reduce expenses in order to conserve its cash in amounts sufficient to sustain operations and meet its obligations.

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

**Note 3 — Summary of Significant Accounting Policies**

During the three and six months ended June 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, valuation of the intangible asset, useful life of the amortizable intangible assets, accrued research and development expenses, stock-based compensation, 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. Management's determination that the Company operated as two segments during the second 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 (see Note 14).

***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 June 30, 2023.

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

***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. The Company has not recorded any impairment losses on long-lived assets.

***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 June 30, 2023, and December 31, 2022:

| | June 30, 2023 | December 31, 2022 |
|---|---|---|
| Raw materials | $ 250,000 | $ - |
| Work-in-process | 921,900 | |
| **Total** | **$ 1,171,900** | **$ -** |

**Prepaid Expenses and Other Current Assets**

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

| | June 30, 2023 | December 31, 2022 |
|---|---|---|
| Prepaid research and development | $ 173,134 | $ 231,981 |
| Prepaid insurance | 347,213 | 148,789 |
| Prepaid other | 165,066 | 88,462 |
| **Total** | **$ 685,413** | **$ 469,232** |

**Accrued Expenses**

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

| | June 30, 2023 | December 31, 2022 |
|---|---|---|
| Accrued research and development | $ 475,434 | $ 847,747 |
| Accrued deferred offering costs | 125,000 | 125,000 |
| Accrued compensation | 349,200 | 1,132,859 |
| Accrued professional fees | 246,314 | — |
| Accrued franchise taxes | 89,600 | 177,600 |
| Other accrued expenses | 134,261 | 125,922 |
| **Total** | **$ 1,419,809** | **$ 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. On September 29, 2023, the Company and Veru entered into an amendment to the ENTADFI® APA, which modified the payment terms of the note payable due on September 30, 2023 (see Note 15).

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.

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 an estimated useful life of five years, starting when ENTADFI® sales begin. 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.

**Note 5 — Acquisitions** (cont.)

*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 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. 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 15).

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 is involved in the day-to-day business activities of the VIE, the Seller has 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 June 30, 2023. The Company recorded the initial $3.5 million payment as a deposit. The Company does not have any liabilities recorded as of June 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 filed for bankruptcy under Chapter 11 of the U.S. Bankruptcy Code, 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 (see Note 15). 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 June 30, 2023, and accordingly, the Company recorded a loss on impairment for the $3.5 million deposit during the three and six months ended June 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 six months ended June 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.

*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.

**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.

**Note 6 — Significant Agreements** (cont.)

During the three and six months ended June 30, 2023 the Company incurred related research and development expense (net gain) of approximately ($49,000) and $287,000, respectively, and at June 30, 2023, the Company had approximately $982,000 recorded as related accounts payable. During the three and six months ended June 30, 2022, the Company incurred related research and development expenses of approximately $275,000 and $492,000, respectively.

*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 six months ended June 30, 2023, the Company incurred approximately $11,000 and $19,000, respectively, in costs for research and development related to the Co-Development Agreement. As of June 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 June 30, 2023.

**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 modified the payment terms of the Note due on September 30, 2023 (see Note 15).

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 $0.2 million of associated interest expense during the three and six months ended June 30, 2023.

Future minimum principal payments on the Notes are as follows, for years ending December 31, excluding the impact of the modified payment terms discussed above (see Note 15):

| | |
|---|---|
| 2023 (remaining 6 months) | $ 4,000,000 |
| 2024 | 10,000,000 |
| Total principal payments | 14,000,000 |
| Less debt discount | (839,005) |
| Total debt, net of discount | $ 13,160,995 |

**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.

***Common Stock***

As of June 30, 2023, and December 31, 2022, there were 16,930,457 and 15,724,957 shares of common stock issued, respectively, and 16,413,058 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.

**Note 8 — Stockholders' Equity** (cont.)

***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 three and six months ended June 30, 2023, the Company repurchased 25,032 and 57,670 shares of common stock, respectively, for an aggregate of approximately $26,000 and $59,000, respectively, at an average price of $1.02 per share for both periods. 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 June 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 is 70,849.

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 and 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 in the accompanying condensed statements of operations.

**Note 8 — Stockholders' Equity** (cont.)

*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 six months ended June 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. No preferred investment options have been exercised as of June 30, 2023. Certain of these preferred investment options were exercised at a reduced exercise price in August 2023 (see Note 15).

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.

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.

**Note 8 — Stockholders' Equity** (cont.)

***At the Market Offering Agreement***

On March 29, 2023, the Company entered into an At The Market Offering Agreement (the "ATM Agreement") with H.C. Wainwright & Co., LLC, as sales agent (the "Agent"), to create an at-the-market equity program under which it may sell up to $3,900,000 of shares of the Company's common stock (the "Shares") from time to time through the Agent (the "ATM Offering"). Under the ATM Agreement, the Agent will be entitled to a commission at a fixed rate of 3.0% of the gross proceeds from each sale of Shares under the ATM Agreement. 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 June 30, 2023, no shares have been sold under the ATM Offering.

***Warrants***

The following summarizes activity related to the Company's outstanding warrants, excluding contingent warrants issuable upon exercise of the preferred investment options, for the six months ended June 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 | — | — | |
| Exercised | (646,640) | 0.001 | |
| Cancelled | — | — | |
| Outstanding as of June 30, 2023 | 5,264,274 | 2.66 | 4.2 |
| Warrants vested and exercisable as of June 30, 2023 | 5,264,274 | $ 2.66 | 4.2 |

As of June 30, 2023, the outstanding warrants include 70,849 April 2022 Private Placement Warrants and 5,193,425 August 2022 Private Placement Warrants, which are exercisable into 5,264,274 shares of common stock which had a fair value of $1.13 per share, based on the closing trading price on that day.

Additionally, as of June 30, 2023, and December 31, 2022, the value of the April Contingent Warrants and the August Contingent Warrants (collectively the "Contingent Warrants") was approximately $14,000, and none of the Contingent Warrants have been issued, as no preferred investment options have been exercised.

***Equity Incentive Plans***

The Company's 2019 Equity Incentive Plan (the "2019 Plan") was adopted by the Board and by its stockholders on July 1, 2019. The Company has reserved 1,400,000 shares of common stock for issuance pursuant to the 2019 Plan. There were no share-based awards granted under the 2019 Plan during the three and six months ended June 30, 2023 and 2022.

**Note 8 — Stockholders' Equity** (cont.)

In addition, on February 23, 2022 and in connection with the closing of the IPO, the Board adopted the Company's 2022 Equity Incentive Plan (the "2022 Plan"), which is the successor and continuation of the Company's 2019 Plan. Under the 2022 Plan, the Company may grant stock options, restricted stock, restricted stock units, stock appreciation rights, and other forms of awards to employees, directors and consultants of the Company. Upon its effectiveness, a total of 1,600,000 shares of common stock were reserved for issuance under the 2022 Plan. In August 2022, the number of shares of common stock reserved for issuance under the 2022 Plan was increased to 2,600,000 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 granted during the six months ended June 30, 2023, and the restricted stock granted during the three and six months ended June 30, 2023, were all granted under the 2022 Plan. As of June 30, 2023, there are 804,938 options available for issuance under the 2022 Plan.

***Stock Options***

The following summarizes activity related to the Company's stock options under the 2019 Plan and the 2022 Plan for the six months ended June 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 | (29,528) | 3.11 | — | — |
| Exercised | (45,920) | 0.01 | 45,920 | — |
| Outstanding as of June 30, 2023 | 1,419,592 | 3.26 | 623,040 | 8.1 |
| Options vested and exercisable as of June 30, 2023 | 1,046,689 | $ 2.94 | $ 583,632 | 7.8 |

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

| | For the Six Months Ended June 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 six months ended June 30, 2023 was $1.08. The aggregate fair value of stock options that vested during the three and six months ended June 30, 2023 was approximately $207,000 and $479,000, 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 October 2023, 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.

| | Number of Shares | Weighted Average Weighted Average Grant Date Fair Value |
|---|---|---|
| Nonvested as of December 31, 2022 | — | $ — |
| Granted | 512,940 | 1.01 |
| Vested | — | — |
| Nonvested as of June 30, 2023 | 512,940 | $ 1.01 |

**Note 8 — Stockholders' Equity** (cont.)

***Stock-Based Compensation***

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

| | For the Three Months Ended June 30, | | For the Six Months Ended June 30, | |
|---|---|---|---|---|
| | **2023** | **2022** | **2023** | **2022** |
| Selling, general and administrative | $ 173,151 | $ 932,211 | $ 272,359 | $ 938,628 |
| Research and development | 99,630 | 514,916 | 186,000 | 527,831 |
| **Total** | **$ 272,781** | **$ 1,447,127** | **$ 458,359** | **$ 1,466,459** |

As of June 30, 2023, unrecognized stock-based compensation expense relating to outstanding stock options and unvested restricted stock is approximately $538,000 and $369,000, respectively, which is expected to be recognized over a weighted-average period of 1.78 years and 1.27 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 CEO, ended on April 30, 2023. During the three and six months ended June 30, 2023, the Company incurred rent expense on this lease of approximately $2,000 and $51,000, respectively, and variable lease expense of approximately $4,000 for both periods.

***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 June 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.

**Note 9 — Commitments and Contingencies** (cont.)

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 June 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 June 30, 2023.

***Milestone and Royalty Obligations***

The Company has entered into various license agreements with third parties that obligate the Company to pay certain development, regulatory, and commercial milestones, which aggregate to $115.1 million, as well as royalties based on product sales (see Note 6). As of June 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 June 30, 2023.

***Indemnification***

In the normal course of business, the Company enters into contracts and agreements that contain a variety of representations and warranties and provide for general indemnifications. The Company's exposure under these agreements is unknown because it involves claims that may be made against the Company in the future but have not yet been made. To date, the Company has not paid any claims 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. 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 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 CEO's employment agreement became effective. During the six months ended June 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 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 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 six months ended June 30, 2022, as general and administrative expenses in the accompanying condensed statement of operations.

As of June 30, 2023, the Company has a receivable from related parties of approximately $325,000, net of a reserve of $422,000, of which approximately $315,000 and $10,000 consists primarily of miscellaneous payments made by the Company on the behalf of the Company's former CEO and CBO, respectively. Subsequent to June 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, during 2022 and the first and second quarter of 2023. The $422,000 reserve associated with the related party receivable 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 concluded that the amounts are not likely to be recovered and as a result would not cause an adjustment to previously issued financial statements.

**Note 10 — Related Party Transactions** (cont.)

Further, the credit card misuse described above resulted in a loss on related party receivable of approximately $79,000 and $165,000 during the three and six months ended June 30, 2023, respectively, which was recorded in selling, general, and administrative expenses in the accompanying statements of operations. Subsequent to June 30, 2023, the former CEO repaid the balance of $315,000, which is net of the reserve of $422,000 on related party receivable, and the CBO repaid her balance in full.

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 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 six months ended June 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 six months ended June 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 pre-funded warrants because their exercise requires only nominal consideration for delivery of shares and 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 June 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 Six Months Ended June 30, | |
|---|---|---|
| | **2023** | **2022** |
| Unvested shares of restricted stock | 512,940 | — |
| Options to purchase shares of common stock | 1,419,592 | 1,495,180 |
| Warrants | 5,264,274 | 1,362,772 |
| **Total** | **7,196,806** | **2,857,952** |

**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 is an employee savings and retirement plan to which substantially all employees may contribute, including the Company's named executive officers, effective July 1, 2023. Pursuant to the 401(k) Plan, employee and Company contributions will vest immediately, subject to a three-month waiting period for new hires. The Company will be required to contribute 3% of gross pay to eligible employees' 401(k) Plans.

**Note 14 — Segment Reporting**

Reportable segments are presented in a manner consistent with the internal reporting provided to the Company's CEO, who was the CODM as of June 30, 2023. The CODM allocates resources to and assesses the performance of each segment using information about its operating loss. During the second quarter of 2023, the Company managed its operations through two segments, research and development and commercial. The research and development segment is the Company's historical business, and is dedicated to the research and development of transformational vaccines to prevent infectious diseases. The commercial segment was new in the second quarter of 2023, and is dedicated to the commercialization of the Company's FDA-approved products, this currently being ENTADFI®. Neither segment has generated any revenue to date. The Company separately presents the costs associated with certain corporate functions as Corporate, primarily consisting of unallocated operating expenses including costs that were not specific to a particular segment but are general to the group, expenses incurred for administrative and accounting staff, directors' and officers' insurance, professional fees and other similar corporate expenses. There is no inter-segment allocation of non-operating expenses, interest and income taxes.

The Company's operating loss by reportable segment is as follows:

| | For the Three Months Ended June 30, 2023 | For the Six Months Ended June 30, 2023 |
|---|---|---|
| Research and development | $ 846,853 | $ 1,929,089 |
| Commercial | 505,886 | 505,886 |
| Corporate | 5,296,861 | 7,062,884 |
| **Total** | **$ 6,649,600** | **$ 9,497,859** |

Total assets are not presented by operating segment as they are not reviewed by the CODM when evaluating the segments' performance.

**Note 15 — Subsequent Events**

***Significant Commitment***

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 has 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 is through July 14, 2025. On October 12, 2023, the Company terminated the Master Services Agreement and statements of work. The early termination of the statement of work for commercialization is subject to an early termination fee of approximately $280,000 to approximately $692,000. As of the date of termination, the remaining fees due under the subscription services statement of work were approximately $715,000.

**Note 15 — Subsequent Events** (cont.)

***Warrant Exercise***

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" see Note 8), pursuant to which 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 exercised price of $1.09 per share, in exchange for the Company's agreement to issue new PIOs (the "Inducement PIOs") on substantially the same terms as the Existing PIOs as described below, to purchase up to 4,972,428 shares of the Company's common stock (the "Inducement PIO Shares"). The Company received aggregate net proceeds of approximately $2.3 million from the exercise of the Existing PIOs by the Holder and the sale of the Inducement PIOs, 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 these transactions 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 the August Contingent Warrants (see Note 8). 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. The warrants described above will have the same terms as the Inducement PIOs except for an exercise price equal to $1.3625 per share. These transactions closed on August 2, 2023.

***WraSer Bankruptcy and WraSer APA Amendment***

On September 26, 2023, WraSer filed for bankruptcy under Chapter 11 of the U.S. Bankruptcy Code.

On October 4, 2023, the parties agreed to amend the WraSer APA, which amendment is currently pending court approval. The amendment 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 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. If, however, the bankruptcy court requires the Company to complete the transaction, the Company is unlikely to be able to execute its commercialization strategy for the WraSer Assets unless and until the Company is able to resolve significant manufacturing concerns. 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 15 — Subsequent Events** (cont.)

***Veru APA Amendment***

On September 29, 2023, the Company entered into the Veru 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 million 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.

The terms of the Series A Preferred Stock are set forth in a Certificate of Designations of Rights and Preferences of Series A Convertible Preferred Stock of the Company (the "Certificate of Designations"), which was filed with the State of Delaware on September 29, 2023. Pursuant to the Veru 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. 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.

The Series A Preferred Stock issued to Seller 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 Veru 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.

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

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

*The following discussion and analysis of our financial condition and results of operations should be read in conjunction with our financial statements and the related notes to those statements included elsewhere in this Report and with the audited financial statements and the related notes included in our Annual Report on Form 10-K for the fiscal year ended December 31, 2022, as filed with the SEC, on March 9, 2023. In addition to historical financial information, the following discussion and analysis contains forward-looking statements that involve risks, uncertainties, and assumptions. Some of the numbers included herein have been rounded for the convenience of presentation. Our actual results may differ materially from those anticipated in these forward-looking statements as a result of many factors. See "Cautionary Note Regarding Forward-Looking Statements."*

**Overview**

We are a biotechnology company focused on developing transformational therapies to address significant health challenges globally. We own ENTADFI®, an FDA-approved, once daily pill that combines finasteride and tadalafil for the treatment of benign prostatic hyperplasia ("BPH"). This combination allows men to receive treatment for their symptoms of BPH without the negative sexual side effects typically seen in patients on finasteride alone. We also hold exclusive, global rights to novel technology licensed from renowned research institutions around the world, including St. Jude, the University of Oxford, CHMC, and UT Health. We believe that our pipeline and vaccine platform are synergistic for developing next generation preventive vaccines to improve both health outcomes and quality of life globally.

Prior to the acquisition of ENTADFI® during the quarter ended June 30, 2023, 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 now operate two business segments: research and development and commercial. The research and development segment is our historical business, and is dedicated to the research and development of transformational vaccines to prevent infectious diseases. The commercial segment is new in the second quarter of 2023 and is dedicated to the commercialization of our FDA-approved products, this currently being ENTADFI®.

Since March 31, 2023, some key developments affecting our business include:

- ***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, Mr. 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 NASDAQ, and four life sciences companies. 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.

- ***Completed Acquisition of ENTADFI®, an FDA-Approved Benign Prostatic Hyperplasia Asset***: On April 19, 2023, the Company entered into an Asset Purchase Agreement (the "Veru APA") with Veru Inc. ("Veru"), pursuant to which the Company purchased substantially all of the assets related to Veru's ENTADFI® product and assumed certain liabilities of Veru. Under this agreement, as amended, the Company purchased ENTADFI® for a total consideration of up to $100 million, including $17 million payable in defined tranches through September 2024 and the issuance of 3,000 shares of Series A convertible preferred stock, and the possibility of an additional $80 million based on predetermined annual sales milestones.

- ***Announced Corporate Name Change in Connection with Acquisition of ENTADFI® and Transition to Commercial-Stage Company:*** On April 24, 2023, the Company announced a corporate name change to Blue Water Biotech, Inc., after the purchase of the FDA-approved asset, ENTADFI® and transition into a commercial-stage pharmaceutical company. Blue Water's commercial team is highlighted by Senior Vice President of Marketing and Business Development, Frank Jaeger, who brings decades of commercial and product launch experience to the team.

- ***Presented Company Overview and Commercial Acquisition Updates at Various Scientific and Investor Conferences:*** Throughout the second quarter, Blue Water management participated in and presented at various scientific and investor conferences to discuss the Company overview and provide an update on recent business activities. For example, Blue Water management participated in the American Urological Association Meeting 2023 to promote ENTADFI® in April 2023 and Blue Water's commercial team presented its launch plans for ENTADFI® at the JMP Securities Life Science Conference in New York, NY in May 2023.

- ***Signed Key Agreements to Execute Commercial Launch Plans for ENTADFI®:*** Since the purchase of ENTADFI® in April 2023, Blue Water has outlined official launch plans for the products and has signed multiple key agreements to execute on such plans. Key agreements and partnerships 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 ("PBM") 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.

- ***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.

- ***Entered Into Definitive Warrant Exercise Agreement:*** In August 2023, the Company closed the exercise of certain existing warrants to purchase 2,486,214 shares of its common stock at a reduced exercise price of $1.09 per share, in exchange for new warrants. The aggregate net proceeds from the exercise of the existing warrants was approximately $2.3 million, after deducting placement agent fees and other offering expenses payable by the Company.

- ***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.

Since our inception in October 2018 until April 2023, when we acquired ENTADFI®, we have devoted substantially all of our resources to performing research and development, undertaking preclinical studies and enabling manufacturing activities in support of our product development efforts, hiring personnel, acquiring and developing our technology and vaccine candidates, organizing and staffing our company, performing business planning, establishing our intellectual property portfolio and raising capital to support and expand such activities.

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. In July 2023, we entered into a Licensing and Services Master 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. In addition, a second statement of work was entered into with the same vendor for certain subscription services providing prescription market data access to the Company. However, on October 12, 2023, the Company terminated the Master Services Agreement and associated statements of work. The early termination of the statement of work for commercialization is subject to an early termination fee of approximately $280,000 to approximately $692,000. As of the date of termination, the remaining fees due under the subscription services statement of work were approximately $715,000. 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 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 June 30, 2023, the Company had a working capital deficit of approximately $0.7 million and an accumulated deficit of approximately $29.1 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 vaccine development, we are unable to predict the timing or amount of increased expenses or when or if we will be able to achieve or maintain profitability from our vaccine program. 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 the Nasdaq Stock Market 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 the Nasdaq Stock Market 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 Convertible Preferred Stock (the "Series A Preferred Stock") of the Company.

The terms of the Series A Preferred Stock are set forth in a Certificate of Designations of Rights and Preferences of Series A Convertible Preferred Stock of the Company (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 Securities and Exchange Commission.

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 June 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. 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 filed for bankruptcy under Chapter 11 of the U.S. Bankruptcy Code.

On October 4, 2023, the parties agreed to amend the WraSer APA, which amendment is currently pending court approval. The amendment 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. If, however, the bankruptcy court requires us to complete the transaction, we are unlikely to be able to execute on our commercialization strategy for the WraSer Assets unless and until we are able to resolve significant manufacturing concerns. 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. If we do not complete our purchase of the WraSer Assets and the Wraser APA is terminated, we will not be able to recover any such costs. Any claims we make for such payment will be general unsecured claims.

**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 Exercise**

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 which 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 exercised price of $1.09 per share, in exchange for the Company's agreement to issue new PIOs (the "Inducement PIOs") on substantially the same terms as the Existing PIOs as described below, to purchase up to 4,972,428 shares of the Company's common stock (the "Inducement PIO Shares"). The Company received aggregate net proceeds of approximately $2.3 million from the exercise of the Existing PIOs by the Holder and the sale of the Inducement PIOs, 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 these transactions and will pay 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. The Company also agreed to issue to Wainwright or its designees warrants (the "Placement Agent Warrants", and such shares of common stock issuable thereunder, the "Placement Agent Warrant Shares") to purchase (i) 149,173 shares of common stock which will have the same terms as the Inducement PIOs except for an exercise price equal to $1.3625 per share and (ii) 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, which will have the same terms as the Inducement PIOs except for an exercise price equal to $1.3625 per share. These transactions closed on August 2, 2023.

**Nasdaq Notice**

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.

***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<br>EP2440582B1<br>JP5894528B2 |
| 13/924,906 | 9,096,644 | Method of treatment | 9/20/2030 | CN107043408B<br>EP2440582B1<br>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. The OUI license includes:

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

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

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

*St. Jude Children's Research Hospital, Inc. Agreement*

On January 27, 2020, we entered into an exclusive, worldwide license agreement with St. Jude, pursuant to which we acquired the right to develop certain licensed products and produce vaccines for use in humans.

Under the St. Jude Agreement, we agreed to pay an initial license fee, an annual maintenance fee, milestone payments, patent reimbursement, and running royalties based on the net sales of licensed products. On May 11, 2022, the Company and St. Jude entered into the St. Jude Amendment. The St. Jude Amendment provides for a revised development milestone timeline, a one-time license fee of $5,000, and an increase to the royalty rate from 4% to 5%. The St. Jude Amendment also provides for an increase to the contingent milestone payments, from $1.0 million to $1.9 million in the aggregate; specifically, development milestones of $0.3 million, regulatory milestones of $0.6 million, and commercial milestones of $1.0 million. On March 22, 2023, the Company entered into another amendment to the St. Jude Agreement, whereby the development milestone timeline was further revised. For additional details regarding our relationship with St. Jude, see Notes 6 and 9 to our financial statements included elsewhere in this Report. The St. Jude license includes:

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

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

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

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

*AbVacc Co-Development Agreement*

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

*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 ("SOW 1") 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 SOW 1. SOW 1 expires September 6, 2026.

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 ("SOW 2"). The fees under SOW 2 total approximately $800,000 and it expires July 14, 2025.

On October 12, 2023, the Company terminated the Master Services Agreement and the statements of work thereunder. The early termination of SOW 1 is subject to an early termination fee of approximately $280,000 to approximately $692,000. As of the date of termination, the remaining fees due under SOW 2 were approximately $715,000.

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

We do not allocate our 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 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 June 30, 2023 and 2022***

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

| | Three Months Ended June 30, 2023 | Three Months Ended June 30, 2022 | $ Change | % Change |
|---|---|---|---|---|
| Operating expenses | | | | |
| Selling, general and administrative | $ 2,302,747 | $ 3,001,418 | (698,671) | (23.3)% |
| Research and development | 846,853 | 1,293,467 | (446,614) | (34.5)% |
| Impairment of deposit on asset purchase agreement | 3,500,000 | - | 3,500,000 | 100.0% |
| Total operating expenses | 6,649,600 | 4,294,885 | 2,354,715 | 54.8% |
| Loss from operations | (6,649,600) | (4,294,885) | (2,354,715) | (54.8)% |
| Total other income (expense) | (215,670) | 30,303 | (245,973) | (811.7)% |
| Net loss | $ (6,865,270) | $ (4,264,582) | (2,600,688) | (61.0)% |

***Selling, General and Administrative Expenses***

For the three months ended June 30, 2023, selling, general and administrative expenses decreased by $0.7 million compared to the same period in 2022. The decrease was mainly due to a decrease in employee compensation of approximately $1.0 million, primarily related to lower stock-based compensation expense and a decrease in executive bonuses in the current period, as well as a decrease of $0.5 million related to a loss contingency incurred in the three months ended June 30, 2022, with no similar expense in the current period. These decreases were offset by an increase in professional fees of approximately $0.3 million, and approximately $0.5 million incurred on commercialization activities for ENTADFI® during the current period.

***Research and Development Expenses***

For the three months ended June 30, 2023, research and development expenses decreased by approximately $0.4 million compared to the same period in 2022. The decrease was mainly due to a decrease in employee compensation, which was primarily related to lower stock-based compensation expense in the current period.

***Impairment of Deposit on Asset Purchase Agreement***

During the three months ended June 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 three months ended June 30, 2023, primarily relates to interest expense incurred on new notes payable issued in April 2023, related to the acquisition of ENTADFI®. Other income recorded during the three months ended June 30, 2022, relates to the change in fair value of the contingent warrant liability, which was issued at the close of the April 2022 private placement, and which was a trivial amount in the current period.

***Comparison of the Six Months Ended June 30, 2023 and 2022***

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

| | Six Months Ended June 30, 2023 | Six Months Ended June 30, 2022 | $ Change | % Change |
|---|---|---|---|---|
| Operating costs and expenses | | | | |
| Selling, general and administrative | $ 4,068,770 | $ 4,616,987 | $ (548,217) | (11.9)% |
| Research and development | 1,929,089 | 1,748,559 | 180,530 | 10.3% |
| Impairment of deposit on asset purchase agreement | 3,500,000 | - | 3,500,000 | 100.0% |
| Total operating expenses | 9,497,859 | 6,365,546 | 3,132,313 | 49.2% |
| Loss from operations | (9,497,859) | (6,365,546) | (3,132,313) | (49.2)% |
| Total other income (expense) | (214,055) | 30,303 | (244,358) | (806.4)% |
| Net loss | $ (9,711,914) | $ (6,335,243) | $ (3,376,671) | (53.3)% |

***Selling, General and Administrative Expenses***

For the six months ended June 30, 2023, selling, general and administrative expenses decreased by $0.5 million compared to the same period in 2022. The decrease was mainly due to a decrease in employee compensation of approximately $1.2 million, primarily related to lower stock-based compensation expenses and a decrease in executive bonuses in the current period. In addition, there was a decrease of $0.5 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 three months ended June 30, 2022, with no similar expense in the current period. These decreases were offset by an increase in professional fees of approximately $0.6 million, an increase in various business activities related to company growth and development, as well as due to now being a public company, such as business advisory services, and rent expense totaling approximately $0.2 million, $0.5 million incurred on commercialization activities for ENTADFI®, and $0.2 million incurred for the loss on related party receivable during the current period.

***Research and Development Expenses***

For the six months ended June 30, 2023, research and development expenses increased by approximately $0.2 million compared to the same period in 2022. The increase was primarily attributable to an increase in preclinical development activities related to BWV-101 of approximately $0.4 million, offset by a decrease in external research and development personnel costs of approximately $0.2 million.

***Impairment of Deposit on Asset Purchase Agreement***

During the six months ended June 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 six months ended June 30, 2023, primarily relates to interest expense incurred on new notes payable issued in April 2023, related to the acquisition of ENTADFI®. Other income recorded during the six months ended June 30, 2022, relates to the change in fair value of the contingent warrant liability, which was issued at the close of the April 2022 private placement, and which was a trivial amount in the current period.

**Liquidity and Capital Resources**

Since inception, we have devoted substantially all of our efforts to research and development, undertaking preclinical studies and enabling manufacturing activities in support of our product development efforts, hiring personnel, acquiring and developing our technology and vaccine candidates, organizing and staffing our company, performing business planning, establishing our intellectual property portfolio, beginning commercialization efforts for ENTADFI®, and raising capital to support and expand such activities. We do not have any products approved for sale, aside from ENTADFI®, and have not generated any revenue from product sales.

We have incurred net losses in each year since inception and expect to continue to incur net losses in the foreseeable future. Our net loss was $6.9 million and $9.7 million for the three and six months ended June 30, 2023, respectively. As of June 30, 2023, we had an accumulated deficit of $29.1 million. We also generated negative operating cash flows of $6.2 million for the six months ended June 30, 2023. During April 2023, the Company completed an acquisition of assets relating to ENTADFI® that requires the Company to pay initial consideration of $20.0 million, of which $6.0 million was paid upon close, and $9.0 million of the remainder was originally due to the seller of the assets within one year of the date the accompanying condensed financial statements were issued. The remaining $5.0 million is due in September 2024. On September 29, 2023, the Company entered into the Amendment. 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 the Seller of $1 million in immediately available funds 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.

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, WraSer filed for bankruptcy under Chapter 11 of the U.S. Bankruptcy Code. On October 4, 2023, the parties agreed to amend the WraSer APA, which amendment is currently pending court approval. The amendment 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. If, however, the bankruptcy court requires us to complete the transaction, we are unlikely to be execute on our commercialization strategy for the WraSer Assets unless and until we are able to resolve significant manufacturing concerns. 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. If we do not complete our purchase of the WraSer Assets and the Wraser APA is terminated, we will not be able to recover any such costs. Any claims we make for such payment will be general unsecured claims.

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, obtaining required licensure is various jurisdictions, and building a salesforce, as well as attempting to secure additional required funding through equity or debt financings if available. However, we may not be able to obtain additional financing on terms favorable to us, if at all, 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 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 financings may subject us to covenant limitations or restrictions on our ability to take specific actions, such as incurring additional debt, making capital expenditures or declaring dividends. Our ability to raise additional funds may be adversely impacted by deteriorating global economic conditions and the recent disruptions to and volatility in the credit and financial markets in the United States and worldwide resulting from the ongoing COVID-19 pandemic. There can be no assurance that we will be successful in acquiring additional funding at levels sufficient to fund our operations or on terms favorable or acceptable to us. If we are unable to obtain adequate financing when needed or on terms favorable or acceptable to us, we may be forced to delay, reduce the scope of our business activities.

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

- the timing, scope, progress, results and costs of research and development, testing, screening, manufacturing, preclinical and non-clinical studies and clinical trials, including any impacts related to the COVID-19 pandemic;
- the outcome, timing and cost of seeking and obtaining regulatory approvals from the FDA and comparable foreign regulatory authorities, including the potential for such authorities to require that we perform field efficacy studies, require more studies than those that we currently expect or change their requirements regarding the data required to support a marketing application;
- the cost of building a sales force in anticipation of any product commercialization;
- the costs of future commercialization activities, including product manufacturing, marketing, sales, royalties and distribution, for ENTADFI® and other products for which we have received or will receive marketing approval;
- our ability to maintain existing, and establish new, strategic collaborations, licensing or other arrangements and the financial terms of any such agreements, including the timing and amount of any future milestone, royalty or other payments due under any such agreement;
- any product liability or other lawsuits related to our products;
- the expenses needed to attract, hire and retain skilled personnel;
- the revenue, if any, received from commercial sales, or sales to foreign governments, of ENTADFI® or 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:

| | Six Months Ended June 30, 2023 | Six Months Ended June 30, 2022 |
|---|---|---|
| Net cash used in operating activities | $ (6,228,769) | $ (4,060,668) |
| Net cash used in investing activities | (10,037,628) | (17,179) |
| Net cash provided by (used in) financing activities | (263,615) | 24,391,556 |
| Net increase (decrease) in cash | $ (16,530,012) | $ 20,313,709 |

***Cash Flows from Operating Activities***

Net cash used in operating activities for the six months ended June 30, 2023 was approximately $6.2 million, which primarily resulted from a net loss of $9.7 million, and a net change in our operating assets and liabilities of $0.9 million. These changes were partially offset by an impairment loss of $3.5 million related to the deposit on the WraSer APA, noncash stock-based compensation of approximately $0.5 million, the loss on related party receivable of approximately $0.2 million, and noncash interest expense of approximately $0.2 million.

Net cash used in operating activities for the six months ended June 30, 2022 was approximately $4.1 million, which primarily resulted from a net loss of approximately $6.3 million, which was partially offset by noncash stock-based compensation of approximately $1.5 million, and a net change in our operating assets and liabilities of approximately $0.8 million.

***Cash Flows from Investing Activities***

Net cash used in investing activities for the six months ended June 30, 2023 was approximately $10.0 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 June 30, 2023, and $0.4 is the net change in the receivable from related parties.

Net cash used in investing activities for the six months ended June 30, 2022 was approximately $17,000, 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 used in financing activities for the six months ended June 30, 2023 was $264,000, and resulted from $59,000 in purchases of treasury shares and $205,000 of payment in deferred offering costs.

Net cash provided by financing activities for the six months ended June 30, 2022 was approximately $24.4 million, and resulted primarily from the close of our IPO and the April Private Placement.

**Legal Contingencies**

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

**Off-Balance Sheet Arrangements**

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

**Recent Accounting Pronouncements Not Yet Adopted**

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

**Critical Accounting Policies and Estimates**

Our financial statements have been prepared in accordance with U.S. GAAP. The preparation of these financial statements requires us to make estimates and judgments that affect the reported amounts of assets, liabilities, and expenses and the disclosure of contingent assets and liabilities in our financial statements. On an ongoing basis, we evaluate our estimates and judgments. We base our estimates on historical experience, known trends and events and various other factors that are believed to be reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources. Actual results may differ from these estimates under different assumptions or conditions. As of June 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.

**JOBS Act**

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

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

- be exempt from the provisions of Section 404(b) of the Sarbanes-Oxley Act, which requires that our independent registered public accounting firm provide an attestation report on the effectiveness of our internal control over financial reporting;

- be permitted to omit the detailed compensation discussion and analysis from proxy statements and reports filed under the Exchange Act and instead provide a reduced level of disclosure concerning executive compensation; and

- be exempt from any rules that may be adopted by the Public Company Accounting Oversight Board requiring mandatory audit firm rotation or a supplement to the auditor's report on the financial statements.

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

**Related Party Transactions**

As of June 30, 2023, the Company has a receivable from the Company's former CEO of approximately $315,000, which is net of the reserve of $422,000, and which consists primarily of miscellaneous payments made by the Company on the behalf of the CEO. Subsequent to June 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 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. Subsequent to June 30, 2023, the former CEO repaid the balance of $315,000, which is net of the reserve of $422,000 on related party receivable.

**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 June 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 June 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 June 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 June 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, other than the identification of the material weaknesses described above.

## 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 June 30, 2023, the Company had cash of approximately $9.2 million, a working capital deficit of approximately $0.7 million and an accumulated deficit of approximately $29.1 million. During April 2023, the Company completed an acquisition of assets that requires the Company to pay initial consideration of $20.0 million, of which $6.0 million was paid upon close, and $9.0 million of the remainder was originally due to the seller of the assets within one year of the date these accompanying condensed financial statements were issued. The remaining $5.0 million is due in September 2024. On September 29, 2023, the Company entered into the Amendment. 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 the Seller of $1 million in immediately available funds 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,

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, and building a salesforce, as well as attempting to secure additional required funding through equity or debt financings if available. However, there are currently no commitments in place for further financing nor is there any assurance that such financing will be available to the Company on favorable terms, if at all. If the Company is unable to secure additional capital, it may be required to curtail any clinical trials, development and/or commercialization of products and product candidates, and it may take additional measures to reduce expenses in order to conserve its cash in amounts sufficient to sustain operations and meet its obligations. These conditions raise substantial doubt about the Company's ability to continue as a going concern for a period of time within one year after the date of the issuance of the condensed financial statements included elsewhere in this Report.

***We 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.***

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. If 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. Due to the WraSer bankruptcy filing and our status as an unsecured creditor of WraSer, we do not expect 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 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. On September 26, 2023, WraSer filed for bankruptcy under Chapter 11 of the U.S. Bankruptcy Code. On October 4, 2023, we amended the WraSer APA, subject to bankruptcy court approval. 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. If, however, the bankruptcy court requires us to complete the transaction, we are unlikely to be able to execute on our commercialization strategy for the WraSer Assets unless and until we are able to resolve significant manufacturing concerns. 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. If we do not complete our purchase of the WraSer Assets and the Wraser APA is terminated, we will not be able to recover any such costs. Any claims we make for such payment will be general unsecured claims.

***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 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 six months ended June 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 have an adverse impact on our vaccine candidates.***

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.

- There was a failure to properly identify fraud risks in our risk assessment process, which led to a lack of appropriate review and monitoring controls over the identification and reporting of personal expenses charged to the Company's corporate credit cards.
- There was a lack of appropriate controls over the approval and reporting of expenses paid with the Company's credit cards and certain bank wires.
- There was a lack of 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 his assistant, and the assistant was responsible for the reconciliation of credit card statements and bank statements. This allowed these individuals to submit unauthorized payments to unauthorized third parties.
- The Company did not maintain effective monitoring controls related to the evaluation and testing of our internal controls over financial reporting.
- 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 or and production of ENTADFI®. While we may be able to identify replacement third-party manufacturers or develop our own manufacturing capabilities for ENTADFI®, this process would likely cause a delay in the availability of ENTADFI® and an increase in costs. In addition, third-party manufacturers may have a limited number of facilities in which ENTADFI® can be produced, and any interruption of the operation of those facilities due to events such as equipment malfunction or failure or damage to the facility by natural disasters could result in the cancellation of shipments, loss of product in the manufacturing process or a shortfall in ENTADFI®

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

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

***If our shares become subject to the penny stock rules, it would become more difficult to trade our shares.***

The SEC has adopted rules that regulate broker-dealer practices in connection with transactions in penny stocks. Penny stocks are generally equity securities with a price of less than $5.00, other than securities registered on certain national securities exchanges or authorized for quotation on certain automated quotation systems, provided that current price and volume information with respect to transactions in such securities is provided by the exchange or system. If we do not retain a listing on Nasdaq and if the price of our common stock is less than $5.00, our common stock will be deemed a penny stock. The penny stock rules require a broker-dealer, before a transaction in a penny stock not otherwise exempt from those rules, to deliver a standardized risk disclosure document containing specified information. In addition, the penny stock rules require that before effecting any transaction in a penny stock not otherwise exempt from those rules, a broker-dealer must make a special written determination that the penny stock is a suitable investment for the purchaser and receive (i) the purchaser's written acknowledgment of the receipt of a risk disclosure statement; (ii) a written agreement to transactions involving penny stocks; and (iii) a signed and dated copy of a written suitability statement. These disclosure requirements may have the effect of reducing the trading activity in the secondary market for our common stock, and therefore stockholders may have difficulty selling their shares.

For additional risks relating to our operations, see the section titled "Risk Factors" contained in our Annual Report on Form 10-K, filed with the SEC on March 9, 2023. Any of these factors could result in a significant or material adverse effect on our results of operations or financial condition. Additional risk factors not presently known to us or that we currently deem immaterial may also impair our business or results of operations.

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

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

**Issuer Purchases of Equity Securities**

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

Below is a summary of stock repurchases for the three months ended June 30, 2023. *See Note 8 to our unaudited condensed financial statements included elsewhere in this Report for more information regarding our stock repurchase program.*

| Period | Total Number of Shares Repurchased | Average Price Paid Per Share | Total Number of Shares Purchased as Part of Publicly Announced Plan | Maximum Number of Shares that May Yet be Purchased Under the Plan (1) |
|---|---|---|---|---|
| Beginning repurchase authority | 492,367 | | 492,367 | 4,507,633 |
| April 1 – April 30, 2023 | | | | |
| Shares repurchased | 1,080 | $ 1.01 | 1,080 | 4,506,553 |
| May 1 - May 31, 2023 | | | | |
| Shares repurchased | 23,952 | $ 1.01 | 23,952 | 4,482,601 |
| Total | 517,399 | | 517,399 | 4,482,601 |

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

**Item 3. Default Upon Senior Securities**

None.

**Item 4. Mine Safety Disclosures**

Not applicable.

**Item 5. Other Information**

None.

**Item 6. Exhibits, Financial Statement Schedules.**

The following documents are filed as exhibits to this Report.

**EXHIBIT INDEX**

| Exhibit Number | Description of Document |
|---|---|
| 3.1 | Certificate of Amendment to the Company's Second Amended and Restated Certificate of Incorporation (incorporated by reference to the Registrant's Current Report on Form 8-K filed with the SEC on April 24, 2023). |
| 3.2 | Second 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 April 24, 2023). |
| 3.1 | 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 | Patent & Technology License Agreement, dated November 18, 2022, between the Company and the University of Texas Health Science Center at San Antonio (incorporated by reference to the Registrant's Quarterly Report on Form 10-Q filed with the SEC on May 12, 2023). |
| 10.2 | Co-Development Agreement, dated February 1, 2023, between the Company and AbVacc, Inc. (incorporated by reference to the Registrant's Quarterly Report on Form 10-Q filed with the SEC on May 12, 2023). |
| 10.3 | At-the-Market Offering Agreement, dated March 29, 2023, between the Company and H.C. Wainwright & Co., LLC (incorporated by reference to the Registrant's Current Report on Form 8-K filed with the SEC on March 29, 2023). |
| 10.4† | Asset Purchase Agreement, dated April 19, 2023, between the Company and Veru Inc. (incorporated by reference to the Registrant's Current Report on Form 8-K filed with the SEC on April 20, 2023). |
| 10.5 | 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). |
| 10.6 | 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). |
| 10.7 | 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). |
| 10.8 | 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). |
| 10.9 | Form of Non-Competition and Non-Solicitation Agreement, dated April 19, 2023 (incorporated by reference to the Registrant's Current Report on Form 8-K filed with the SEC on April 20, 2023). |
| 10.10 | Promissory Note, dated April 19, 2023 (incorporated by reference to the Registrant's Post-Effective Amendment No. 1 to Form S-1 on Form S-3 filed with the SEC on April 28, 2023). |
| 10.11 | Promissory Note, dated April 19, 2023 (incorporated by reference to the Registrant's Post-Effective Amendment No. 1 to Form S-1 on Form S-3 filed with the SEC on April 28, 2023). |
| 10.12† | 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 Current Report on Form 8-K filed with the SEC on June 14, 2023). |
| 10.13† | Management Services Agreement, dated June 13, 2023, by and among WraSer, LLC, Xspire Pharma, LLC, and Blue Water Biotech, Inc. (incorporated by reference to the Registrant's Current Report on Form 8-K filed with the SEC on June 14, 2023). |
| 10.14* | 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. |
| 31.1* | Certification of the Principal Executive Officer pursuant to Rule 13a-14(a) and Rule 15d-14(a) under the Securities Exchange Act of 1934, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002. |
| 31.2* | Certification of the Principal Financial Officer pursuant to Rule 13a-14(a) and Rule 15d-14(a) under the Securities Exchange Act of 1934, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002. |
| 32.1** | Certification of the Principal Executive Officer pursuant to 18 U.S.C. 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002. |
| 32.2** | Certification of the Principal Financial Officer pursuant to 18 U.S.C. 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002. |
| 101.INS* | Inline XBRL Instance Document. |
| 101.SCH* | Inline XBRL Taxonomy Extension Schema Document. |
| 101.CAL* | Inline XBRL Taxonomy Extension Calculation Linkbase Document. |
| 101.DEF* | Inline XBRL Taxonomy Extension Definition Linkbase Document. |
| 101.LAB* | Inline XBRL Taxonomy Extension Label Linkbase Document. |
| 101.PRE* | Inline XBRL Taxonomy Extension Presentation Linkbase Document. |
| 104 | Cover Page Interactive Data File (formatted as Inline XBRL and contained in Exhibit 101). |

* Filed herewith.

** Furnished herewith.

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

**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: October 20, 2023

/s/ Dr. Neil Campbell
Dr. Neil Campbell
(principal executive officer)

Date: October 20, 2023

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

**FORM OF AMENDMENT TO**
**ASSET PURCHASE AGREEMENT**

This Amendment to Asset Purchase Agreement (the "Amendment") is made effective as of October 4, 2023 by and between WraSer, LLC, a Mississippi limited liability company and Xspire Pharma, LLC, a Mississippi limited liability company (collectively, the "**Seller**"), Legacy-Xspire Holdings, LLC, a Delaware limited liability company and the parent company of the Seller ("**Parent**") and Blue Water Biotech, Inc., a Delaware corporation ("**Buyer**"). Seller and Buyer are sometimes referred to herein individually as a "**Party**" and collectively as the "**Parties**."

**WITNESSETH:**

**WHEREAS,** the Parties entered into that certain Asset Purchase Agreement (the "**APA**"), dated June 13, 2023; and

**WHEREAS,** the parties desire to modify certain terms of the APA as more fully described herein.

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

**I. Amendments to APA**

1. Section 2.3.1 of the APA is hereby amended and restated in its entirety by the following:

**2.3.1** Closing Purchase Price. Upon the terms and subject to the conditions of this Agreement, in consideration of the conveyances contemplated under Section 2.1, Buyer shall:

(a) On the Execution Date, pay $3,500,000.00 to Seller, in cash, in immediately available funds, to the account of the Seller previously provided by Seller to Buyer (the "**Signing Cash**"), which will be used to pay off the Accounts Payable set forth on Schedule 2.3.1(a);

(b) On the Closing Date, issue to (or at the direction of) Plexus Fund IV-A, L.P., as collateral agent (the "**Collateral Agent**"), on behalf of the Seller's secured creditors under the Note Purchase Agreement dated as of December 18, 2019 by and among Parent, Seller, the Collateral Agent and the other parties thereto (as amended, the "**Loan Agreement**") (or directly to such secured creditors as designated by Collateral Agent) one million (1,000,000) shares of common stock, par value $0.00001 per share (the "**Common Stock**"), of Buyer and within two (2) business days of the Closing Date, issue to (or at the direction of) Collateral Agent (or directly to such secured creditors as designated by Collateral Agent) seven hundred eighty-nine (789) shares of Series A Convertible Preferred Stock, par value $0.00001 per share, with such designations, rights, powers and preferences set forth in the Certificate of Designation attached hereto as Schedule 2.3.1(a)(ii) (the "**Preferred Stock**") (Collateral Agent agrees not to sell more than 500,000 shares of Common Stock received upon conversion of the Preferred Stock per quarter) (collectively, the Common Stock and Preferred Stock shall be referred to as the "**Shares**"); provided, however if stockholder approval is required by applicable Law to issue the Common Stock and convert the Preferred Stock, issuance or conversion, as applicable, shall not occur until the stockholders approve the issuance and/or conversion, provided, further, that in such case Buyer agrees to use best efforts to obtain such stockholder approval as soon as reasonably practicable. If stockholder approval is not obtained, Buyer shall issue as many Shares to Collateral Agent (or its designees) as are allowed by applicable Law. Any designee of Collateral Agent who receives Shares pursuant to this Agreement shall be entitled to the rights granted to Collateral Agent under Section 4.19 of this Agreement. The Shares will not be registered with the SEC under the Securities Act as of the Closing Date, subject to the provisions of Section 4.19;

(c) On the Closing Date, pay $2,200,000.00 to Seller in cash, in immediately available funds, to the account of Seller previously provided by Seller to Buyer (the "**Closing Cash**");

(d) Beginning on January 30, 2024, monthly payments to the Collateral Agent, on behalf of the Seller's secured creditors under the Loan Agreement, or directly to such secured creditors as designated by the Collateral Agent, for a total monthly amount of $150,000.00, and for an aggregate amount of $2,300,000.00, pursuant to Promissory Notes from Buyer to Collateral Agent, on behalf of the Seller's secured creditors under the Loan Agreement, or directly to such secured creditors as designated by the Collateral Agent, in the form attached hereto as Exhibit C (the "**Promissory Note**") ("**Post-Closing Payment**", together with the Signing Cash, Closing Cash and Shares, shall be referred to as the "**Purchase Price**");

(e) On the Closing Date, Seller may sweep all the cash out of Seller's bank accounts and any amounts in excess of $1,100,000 will be deducted from the Post-Closing Payment; and

(f) On the Closing Date, assume the Assumed Liabilities.

2. Section 2.3.5 of the APA is hereby amended and restated in its entirety by the following:

> Closing Statement. The Seller shall, at least five (5) days prior to the Closing, deliver a closing statement setting forth (i) the closing balance sheet schedule of the Seller that sets forth Accounts Receivable outstanding and Accounts Payable that Buyer is assuming, calculated pursuant to the methodology set forth on Exhibit B (the "**Closing Balance Sheet Statement**") (ii) the Uncollected Execution Date Accounts Receivable, (iii) the Accounts Receivable Target of Seller, (iv) the amount of Cash currently in Seller's bank accounts, and (v) the Seller Accounts Receivable Closing Amount, whichever is applicable (the "**Closing Statement**").

3. Section 3.1.4 of the APA is hereby amended and restated in its entirety by the following:

> No Broker. Except with respect to Stifel, Nicolaus & Company, Incorporated (assignee of Torreya Capital, LLC), whose fees and expenses will be the responsibility of Seller, there is no broker, finder, financial advisor or other Person acting or who has acted on behalf of Seller or any of its Affiliates that is entitled to receive any brokerage or finder's or financial advisory fee from Buyer or any of its Affiliates in connection with the transactions contemplated by this Agreement or any Ancillary Agreement.

4. Definitions. The definitions of Excluded Assets and Products are amended and restated as follows:

> "**Excluded Assets**" means all assets, property, rights and interests of Seller and its Affiliates other than the Purchased Assets, including (a) Cash; (b) all refunds, claims for refunds or rights to receive refunds from any Taxing Authority with respect to any and all Taxes paid or to be paid by Seller or any of its Affiliates (including any and all Taxes paid or to be paid by any of Seller's Affiliates on behalf of Seller) and any funds Seller receives from TriNet Group, Inc. for the Coronavirus Aid, Relief and Economic Security Act payroll tax credits; (c) all insurance policies and insurance Contracts insuring the Purchased Assets, together with any claim, action or other right Seller or any Affiliate of Seller may have for insurance coverage under any past or present policies and insurance Contracts insuring the Purchased Assets; (d) the original global safety database relating to the Product; (e) Butalbital/APAP/Caffeine ANDA A206615; (f) TaperDex (dexamethasone); (g) Dihydrocodeine, Acetaminophen and Caffeine capsules under the trademark Trezix® and its Authorized Generic Version approved under US FDA ANDA A204785; (h) Nalfon capsules under US FDA NDA N017604; (i) Fenoprofen Calcium tablets under US FDA ANDA A072267; (j) Uncollected Execution Date Accounts Receivable and (k) all Excluded Items, but excluding, in each case, the Purchased Assets.
>
> "**Products**" means (i) Ciprofloxacin 0.3% and Fluocinolone Acetonide 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 its Authorized Generic Version approved under US FDA NDA N021918; (iii) intentionally omitted; (iv) Reserved; and (v) Vorapaxar Sulfate tablets under the trademark Zontivity® approved under US FDA NDA N204886.

**II. Buyer Acknowledgement.** Buyer acknowledges that it supports Seller filing a Chapter 11 bankruptcy and seeking bankruptcy court approval for the transaction contemplated by the APA and notwithstanding Section 2.4.1 of the APA, Closing will occur within one (1) business day of bankruptcy court approval, subject to the following conditions.

2.1 Promptly following the execution hereof (and in no event later than five days thereafter), Seller will file an amended motion (the **"Sale Motion"**) for an order (the **"Approval Order"**) from the bankruptcy court which (i) approves the sale of the Purchased Assets to Buyer on the terms and conditions set forth in APA as amended by this Amendment and authorizes the Seller to proceed with this transaction, (ii) includes a specific finding that the Purchase Price was negotiated at arm's length, constitutes fair consideration for the Purchased Assets and that Buyer is a good faith Buyer of the Purchased Assets and protected pursuant to Section 363(m) of the Bankruptcy Code and that the provisions of Section 363(n) of the Bankruptcy Code have not been violated, (iii) includes a specific finding that notice of the hearing on the Sale Motion and any related auction was proper under the Bankruptcy Code, bankruptcy rules and local rules; (iv) includes a specific finding that Buyer is not a successor to Seller or the bankruptcy estate by any reason or theory of law or equity, and that Buyer shall not be subject to successor liability for any products sold prior to Closing; (v) bars any creditor or other person from bringing any claim or asserting any liens against Buyer or the Purchased Assets, except as relates to Assumed Liabilities; and (vi) states that the sale of the Purchased Assets to Buyer shall be free and clear of all liens, claims, interests and encumbrances whatsoever (other than the Permitted Liens) with all such encumbrances attaching the net sale proceeds, if any. Following the filing of the Sale Motion, Seller shall use reasonable efforts to obtain the Approval Order. Both Buyer's and Seller's obligations to consummate the transactions contemplated in this Agreement which the Buyer and Seller may hereafter enter into shall be conditioned upon the bankruptcy court's entry of the Approval Order. If (i) the bankruptcy court refuses to issue the Approval Order at the hearing on the Sale Motion, or (ii) the Seller does not submit an Approval Order for court approval by the bankruptcy court on or before October 9, 2023, then this transaction at Buyer's election in writing shall automatically terminate and release Buyer from all payment obligations to Seller.

**III. Seller Acknowledgement.** Seller agrees to the Closing of the transaction contemplated by the APA, as amended hereby, notwithstanding Buyer's breach of Section 3.2.5 of the APA.

**IV. Miscellaneous**

1. The terms and provisions of this Amendment control, supersede and amend any conflicting terms and provisions contained in the APA. Except for the express modifications made in this Amendment, the APA continues in full force in effect. All references to the APA shall be deemed references to the APA as supplemented and modified hereby.

2. This Amendment may be executed in one or more counterparts and by facsimile or other electronic transmission, each of which shall be deemed an original, and all of which shall constitute one and the same agreement.

3. The Collateral Agent, on behalf of the Seller's secured creditors under the Loan Agreement, shall be a third party beneficiary of the provisions of the APA (as amended hereby) that apply to the Collateral Agent or such secured creditors, including, without limitation, Sections 2.3.1(b), 2.3.1(d), and Section 4.19 of the APA, shall be entitled to the benefit of all rights of the Collateral Agent set forth in such provisions, and shall have the right to enforce such provisions as if it were a party hereto.

*[Remainder of Page Intentionally Left Blank; Signature Page Follows]*

**IN WITNESS WHEREOF,** the parties hereto have caused this Amendment to be executed effective as of the date first written above.

**SELLER:**

**WRASER, LLC**

By: _____
Name: Greg Stokes
Title: Chief Executive Officer

**XSPIRE PHARMA, LLC**

By: _____
Name: Greg Stokes
Title: Chief Executive Officer

**PARENT**:

**LEGACY-XSPIRE HOLDINGS, LLC**

By: _____
Name: Greg Stokes
Title: Chief Executive Officer

**BUYER:**

**BLUE WATER BIOTECH, INC.**

By: _____
Name: Erin Henderson
Title: Chief Business Officer

*[Signature Page to Amendment to Asset Purchase Agreement]*

Schedule 2.3.1(a)(ii)

**CERTIFICATE OF DESIGNATIONS,**

**PREFERENCES AND RIGHTS**

**OF**

**SERIES A CONVERTIBLE PREFERRED STOCK**

**OF**

**BLUE WATER BIOTECH, INC.**

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Pursuant to Section 151 of the General
Corporation Law of the State of Delaware

The undersigned officer of Blue Water Biotech, Inc., a corporation organized and existing under and by virtue of the General Corporation Law of the State of Delaware (the "Corporation"), do hereby certify that:

1. She is the Chief Business Officer of the Corporation.

2. The Corporation is authorized to issue 10,000,000 shares of preferred stock, of which 1,150,000 were authorized as Series Seed Preferred, of which 1,146,138 were issued.

3. That pursuant to the authority conferred upon the Board of Directors by the Amended and Restated Certificate of Incorporation of the Corporation, as amended (the "Certificate of Incorporation"), the Board of Directors authorized the series of preferred stock hereinafter provided for and has adopted the following resolution creating a series of 10,000 shares of preferred stock designated as "Series A Convertible Preferred Stock":

**WHEREAS**, the Certificate of Incorporation provides for a class of its authorized stock known as preferred stock, consisting of 10,000,000 shares, $0.00001 par value per share, issuable from time to time in one or more series;

**WHEREAS**, the Board of Directors has the full and complete authority to establish one or more series or classes and to issue shares of preferred stock, and to fix, determine and vary the voting rights, designations, preferences, restrictions, qualifications, privileges, limitation, options, conversion rights and other special rights of each series or class of preferred stock, including, but not limited to, dividend rates and manner of payment, preferential amounts payable upon voluntary or involuntary liquidation, voting rights, conversion rights, redemption prices, terms and conditions, and sinking fund and stock purchase prices, terms and conditions; and

**WHEREAS**, it is the desire of the Board of Directors, pursuant to its authority as aforesaid, to fix the rights, preferences, restrictions and other matters relating to a series of the preferred stock, which shall consist of up to 10,000 shares of Series A Convertible Preferred Stock which the Corporation has the authority to issue, as follows:

**NOW, THEREFORE, BE IT RESOLVED**, that the Board of Directors does hereby provide for the issuance of a series of Series A Convertible Preferred stock for cash or exchange of other securities, indebtedness, rights or property and does hereby fix and determine the rights, preferences, restrictions and other matters relating to such series of preferred stock as follows:

1. Designation and Amount. The shares of Series A Convertible Preferred Stock shall have a par value of $0.00001 per share and shall be designated as "Series A Convertible Preferred Stock" and the number of shares constituting the Series A Convertible Preferred Stock shall be up to 10,000 shares. The Series A Convertible Preferred Stock (the "Preferred Stock") shall be offered for sale at a purchase price of $1,000 per share and shall have a stated value of $1,000 per share (the "Stated Value").

2. Voting. Except as otherwise provided herein or as otherwise required by law, the Preferred Stock shall have no voting rights. However, as long as any shares of Preferred Stock are outstanding, the Corporation shall not, without the affirmative vote of the holders of a majority of the then outstanding shares of Preferred Stock voting as a separate class, (a) either directly or indirectly, by amendment, merger, consolidation or otherwise, alter, amend or repeal any provision of this Certificate, (b) authorize or create any class of equity securities ranking as to distribution of assets upon a Liquidation (as defined in Section 7) senior to the Preferred Stock, (c) enter into, create, incur, assume or suffer to exist any indebtedness for borrowed money, except for purchase money indebtedness, that by its terms is expressly senior in right of payment to the Corporation's obligations to the holders of Preferred Stock (each such holder, a "Holder" and collectively, the Holders") under this Certificate or (d) enter into any agreement with respect to any of the foregoing.

3. Conversion.

a) Conversions at Option of Holder. Each share of Preferred Stock shall be convertible, at any time and from time to time from and after one (1) year from the date of issuance (the "Original Issue Date") into that number of shares of the Corporation's common stock, par value $0.00001 per share (the "Common Stock") (subject to the limitations set forth in Section 3(d)) determined by dividing the Stated Value of such share of Preferred Stock by the Conversion Price. A Holder shall effect any such conversion by providing the Corporation with the form of conversion notice attached hereto as **Annex A** (a "Notice of Conversion"). Each Notice of Conversion shall specify the number of shares of Preferred Stock to be converted, the number of shares of Preferred Stock owned prior to the conversion at issue, the number of shares of Preferred Stock owned subsequent to the conversion at issue and the date on which such conversion is to be effected, which date may not be prior to the date the applicable Holder delivers by .pdf via email such Notice of Conversion to the Corporation (such date, the "Conversion Date"). If no Conversion Date is specified in a Notice of Conversion, the Conversion Date shall be the date that such Notice of Conversion to the Corporation is deemed delivered hereunder. No ink-original Notice of Conversion shall be required, nor shall any medallion guarantee (or other type of guarantee or notarization) of any Notice of Conversion form be required. The calculations and entries set forth in the Notice of Conversion shall control in the absence of manifest or mathematical error. To effect conversions of shares of Preferred Stock, a Holder shall not be required to surrender the certificate(s) representing the shares of Preferred Stock to the Corporation unless all of the shares of Preferred Stock represented thereby are so converted, in which case such Holder shall deliver the certificate representing such shares of Preferred Stock promptly following the Conversion Date at issue. Shares of Preferred Stock converted into Common Stock or redeemed in accordance with the terms hereof shall be canceled and shall not be reissued.

b) Conversion Price. The conversion price for the Preferred Stock shall equal $0.5254[1], subject to adjustment herein (the "Conversion Price").

c) Mechanics of Conversion

i. Delivery of Conversion Shares Upon Conversion. Not later than five (5) Trading Days after each Conversion Date, the Corporation shall deliver, or cause to be delivered, to the converting Holder such number of Conversion Shares being acquired upon the conversion of the Preferred Stock. As used herein, "Trading Day" means a day on which the NASDAQ Stock Market is open for business.

ii. Reservation of Shares Issuable Upon Conversion. The Corporation covenants that it will at all times reserve and keep available out of its authorized and unissued shares of Common Stock for the sole purpose of issuance upon conversion of the Preferred Stock as herein provided, free from preemptive rights or any other actual contingent purchase rights of Persons other than the Holder (and the other holders of the Preferred Stock), not less than such aggregate number of shares of the Common Stock as shall be issuable (taking into account the adjustments and restrictions of Section 8) upon the conversion of the then outstanding shares of Preferred Stock.

iii. Fractional Shares. No fractional shares or scrip representing fractional shares shall be issued upon the conversion of the Preferred Stock. As to any fraction of a share which the Holder would otherwise be entitled to purchase upon such conversion, the Corporation shall at its election, either pay a cash adjustment in respect of such final fraction in an amount equal to such fraction multiplied by the Conversion Price or round up to the next whole share.

iv. Transfer Taxes and Expenses. The issuance of Conversion Shares on conversion of this Preferred Stock shall be made without charge to any Holder for any documentary stamp or similar taxes that may be payable in respect of the issue or delivery of such Conversion Shares, provided that the Corporation shall not be required to pay any tax that may be payable in respect of any transfer involved in the issuance and delivery of any such Conversion Shares upon conversion in a name other than that of the Holders of such shares of Preferred Stock and the Corporation shall not be required to issue or deliver such Conversion Shares unless or until the Person or Persons requesting the issuance thereof shall have paid to the Corporation the amount of such tax or shall have established to the satisfaction of the Corporation that such tax has been paid. The Corporation shall pay all Transfer Agent fees required for same-day processing of any Notice of Conversion and all fees to the Depository Trust Company (or another established clearing corporation performing similar functions) required for same-day electronic delivery of the Conversion Shares.

1 Conversion Price shall be BWV's closing price on September 28, 2023

(d) Issuance Limitations. Notwithstanding anything herein to the contrary, if the Corporation has not obtained Shareholder Approval (as defined below), then the Corporation may not issue, upon conversion of the Preferred Stock, a number of shares of Common Stock which, when aggregated with any shares of Common Stock issued on or after the Original Issue Date and prior to such Conversion Date, would exceed 3,744,209[2] shares of Common Stock (subject to adjustment for forward and reverse stock splits, recapitalizations and the like) (such number of shares, the "Issuable Maximum"). Each Holder shall be entitled to a portion of the Issuable Maximum equal to the quotient obtained by dividing (x) the original Stated Value of such Holder's Preferred Stock by (y) the aggregate Stated Value of all Preferred Stock issued on the Original Issue Date to all Holders. Such portion shall be adjusted upward ratably in the event a Holder no longer holds any Preferred Stock and the amount of shares issued to such Holder pursuant to such Holder's Preferred Stock was less than such Holder's pro-rata share of the Issuable Maximum. "Shareholder Approval" means the affirmative vote of the holders of the Corporation's capital stock by the required vote under the Delaware General Corporation Law and NASDAQ Listing Rule 5635, and any successor thereto, or any similar rule of any other stock exchange on which the Common Stock may be listed, as applicable, to approve the conversion of the Preferred Stock described herein pursuant to the such rule.

4. Dividends. Holders shall be entitled to receive, and the Corporation shall pay, dividends on shares of Preferred Stock equal (on an as-if-converted-to-Common-Stock basis) to and in the same form as dividends actually paid on shares of the Common Stock when, as and if such dividends are paid on shares of the Common Stock. No other dividends shall be paid on shares of Preferred Stock. Dividends shall cease to accrue with respect to any shares of Preferred Stock that are canceled, retired or redeemed by the Corporation in accordance with this Certificate.

5. Transferability. The holders of Preferred Stock shall not, directly or indirectly, sell, give, assign, hypothecate, pledge, encumber, grant a security interest in or otherwise dispose of (whether by operation of law or otherwise) (each a "Transfer") the Preferred Stock, in whole or in part, or any right, title or interest herein or hereto, except in accordance with the provisions of this Certificate. Any attempt to Transfer the Preferred Stock or any rights hereunder in violation of the preceding sentence shall be null and void ab initio and the Corporation shall not register any such Transfer. Upon the Transfer of the Preferred Stock, in whole or in part, through the use of an assignment form in a form reasonably satisfactory to the Corporation, and in accordance with applicable law or regulation, and the payment by the holder of funds sufficient to pay any transfer tax, the Corporation shall issue and register the Preferred Stock in the name of the new holder or, in the event the Preferred Stock is transferred in part, the Corporation shall deliver new certificates of like tenor registered in the names of each of the current holder and the transferee in amounts that give effect to such partial Transfer. Notwithstanding any other provision of this Certificate, no Transfer may be made pursuant to this Section 5 unless (a) the Transfer complies in all respects with the applicable provisions of this Certificate and (b) the Transfer complies in all respects with applicable federal and state securities laws, including, without limitation, the Securities Act of 1933, as amended (the "Securities Act"). If requested by the Corporation in its reasonable judgment, unless such Transfer has been registered under the Securities Act, the holder shall supply to the Corporation an opinion of counsel, at the holder's expense, to the effect that such Transfer is not required to be registered under the Securities Act.

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2 19.99% of the number of shares of Common Stock outstanding on 9/28/2023

6. Redemption. The Corporation shall have the right to redeem in cash any outstanding shares of Preferred Stock along with accrued but unpaid dividends beginning immediately after issuance of such shares of Preferred Stock. In the event that there is more than one holder of Preferred Stock and the Corporation desires to conduct a redemption, such redemption shall be done on a pro rata basis among all of the holders of Preferred Stock. The Corporation shall effect a redemption by sending a notice to each holder of such Preferred Stock indicating the date of such redemption and the number of shares being redeemed and providing each holder with a check or wire for the redemption amount. The holders shall not be required to return their Preferred Stock certificate following a redemption, such redemption to be reflected on the Company's Preferred Stock registry with evidence of payment of the redemption amount being conclusive evidence of the redemption of shares of Preferred Stock. The holder of Preferred Stock shall not under any circumstances have any right to require redemption. If any shares of Preferred Stock shall be converted, redeemed or reacquired by the Corporation, such shares shall resume the status of authorized but unissued shares of preferred stock and shall no longer be designated as Preferred Stock.

7. Liquidation Preference. Each share of Preferred Stock will have a liquidation preference equal to the Stated Value plus any accrued but unpaid dividends thereon (the "Liquidation Preference"). In the event of a liquidation, dissolution or winding up of the Corporation (which shall include any merger, reorganization, sale of assets in which control of the Corporation is transferred or event which results in all or substantially all of the Corporation's assets being transferred) (a "Liquidation"), the holders of Preferred Stock shall be entitled to receive out of the assets of the Corporation, before any payment is made to the holders of the Corporation's common stock and either in preference to or pari pasu with the holders of any other series of preferred stock that may be issued in the future, a per share amount equal to the Liquidation Preference. If the assets of the Corporation shall be insufficient to pay in full such amounts, then the entire assets to be distributed to the holders of Preferred Stock shall be ratably distributed among the holders in accordance with the respective amounts that would be payable on such shares if all amounts payable thereon were paid in full. Any remaining assets of the Corporation following payment of the Liquidation Preference to the holders of Preferred Stock shall be distributed to the holders of the Corporation's common stock and any junior series of preferred stock then outstanding.

8. Certain Adjustments.

(a) Stock Dividends and Stock Splits. If the Corporation, at any time while this Preferred Stock is outstanding: (i) pays a stock dividend or otherwise makes a distribution or distributions payable in shares of Common Stock on shares of Common Stock, (ii) subdivides outstanding shares of Common Stock into a larger number of shares, (iii) combines (including by way of a reverse stock split) outstanding shares of Common Stock into a smaller number of shares, or (iv) issues, in the event of a reclassification of shares of the Common Stock, any shares of capital stock of the Corporation, then the Conversion Price shall be multiplied by a fraction of which the numerator shall be the number of shares of Common Stock (excluding any treasury shares of the Corporation) outstanding immediately before such event, and of which the denominator shall be the number of shares of Common Stock outstanding immediately after such event. Any adjustment made pursuant to this Section 8(a) shall become effective immediately after the record date for the determination of stockholders entitled to receive such dividend or distribution and shall become effective immediately after the effective date in the case of a subdivision, combination or re-classification.

(b) Pro Rata Distributions. During such time as this Preferred Stock is outstanding, if the Corporation declares or makes any dividend or other distribution of its assets (or rights to acquire its assets) to holders of shares of Common Stock, by way of return of capital or otherwise (including, without limitation, any distribution of cash, stock or other securities, property or options by way of a dividend, spin off, reclassification, corporate rearrangement, scheme of arrangement or other similar transaction) (a "Distribution"), at any time after the issuance of this Preferred Stock, then, in each such case, the Holder shall be entitled to participate in such Distribution to the same extent that the Holder would have participated therein if the Holder had held the number of shares of Common Stock acquirable upon complete conversion of this Preferred Stock (without regard to any limitations on conversion hereof) immediately before the date of which a record is taken for such Distribution, or, if no such record is taken, the date as of which the record holders of shares of Common Stock are to be determined for the participation in such Distribution.

(c) Fundamental Transaction. If, at any time while this Preferred Stock is outstanding, (i) the Corporation, directly or indirectly, in one or more related transactions effects any merger or consolidation of the Corporation with or into another Person, (ii) the Corporation, directly or indirectly, effects any sale, lease, license, assignment, transfer, conveyance or other disposition of all or substantially all of its assets in one or a series of related transactions, (iii) any, direct or indirect, purchase offer, tender offer or exchange offer (whether by the Corporation or another Person) is completed pursuant to which holders of Common Stock are permitted to sell, tender or exchange their shares for other securities, cash or property and has been accepted by the holders of 50% or more of the outstanding Common Stock, (iv) the Corporation, directly or indirectly, in one or more related transactions effects any reclassification, reorganization or recapitalization of the Common Stock or any compulsory share exchange pursuant to which the Common Stock is effectively converted into or exchanged for other securities, cash or property, or (v) the Corporation, directly or indirectly, in one or more related transactions consummates a stock or share purchase agreement or other business combination (including, without limitation, a reorganization, recapitalization, spin-off or scheme of arrangement) with another Person whereby such other Person acquires more than 50% of the outstanding shares of Common Stock (each a "Fundamental Transaction"), then, upon any subsequent conversion of this Preferred Stock, the Holder shall have the right to receive, for each Conversion Share that would have been issuable upon such conversion immediately prior to the occurrence of such Fundamental Transaction (without regard to any limitation in Section 3(d) on the conversion of this Preferred Stock), the number of shares of Common Stock of the successor or acquiring corporation or of the Corporation, if it is the surviving corporation, and any additional consideration (the "Alternate Consideration") receivable as a result of such Fundamental Transaction by a holder of the number of shares of Common Stock for which this Preferred Stock is convertible immediately prior to such Fundamental Transaction (without regard to any limitation in Section 3(d) on the conversion of this Preferred Stock). For purposes of any such conversion, the determination of the Conversion Price shall be appropriately adjusted to apply to such Alternate Consideration based on the amount of Alternate Consideration issuable in respect of one share of Common Stock in such Fundamental Transaction, and the Corporation shall apportion the Conversion Price among the Alternate Consideration in a reasonable manner reflecting the relative value of any different components of the Alternate Consideration. If holders of Common Stock are given any choice as to the securities, cash or property to be received in a Fundamental Transaction, then the Holder shall be given the same choice as to the Alternate Consideration it receives upon any conversion of this Preferred Stock following such Fundamental Transaction. To the extent necessary to effectuate the foregoing provisions, any successor to the Corporation or surviving entity in such Fundamental Transaction shall file a new Certificate of Designation with the same terms and conditions and issue to the Holders new preferred stock consistent with the foregoing provisions and evidencing the Holders' right to convert such preferred stock into Alternate Consideration. The Corporation shall cause any successor entity in a Fundamental Transaction in which the Corporation is not the survivor (the "Successor Entity") to assume in writing all of the obligations of the Corporation under this Certificate of Designation in accordance with the provisions of this Section 8(d) pursuant to written agreements in form and substance reasonably satisfactory to the Holder and approved by the Holder (without unreasonable delay) prior to such Fundamental Transaction and shall, at the option of the holder of this Preferred Stock, deliver to the Holder in exchange for this Preferred Stock a security of the Successor Entity evidenced by a written instrument substantially similar in form and substance to this Preferred Stock which is convertible for a corresponding number of shares of capital stock of such Successor Entity (or its parent entity) equivalent to the shares of Common Stock acquirable and receivable upon conversion of this Preferred Stock (without regard to any limitations on the conversion of this Preferred Stock) prior to such Fundamental Transaction, and with a conversion price which applies the conversion price hereunder to such shares of capital stock (but taking into account the relative value of the shares of Common Stock pursuant to such Fundamental Transaction and the value of such shares of capital stock, such number of shares of capital stock and such conversion price being for the purpose of protecting the economic value of this Preferred Stock immediately prior to the consummation of such Fundamental Transaction). Upon the occurrence of any such Fundamental Transaction, the Successor Entity shall succeed to, and be substituted for (so that from and after the date of such Fundamental Transaction, the provisions of this Certificate of Designation and the other Transaction Documents referring to the "Corporation" shall refer instead to the Successor Entity), and may exercise every right and power of the Corporation and shall assume all of the obligations of the Corporation under this Certificate of Designation and the other Transaction Documents with the same effect as if such Successor Entity had been named as the Corporation herein.

(d) Calculations. All calculations under this Section 8 shall be made to the nearest cent or the nearest 1/100th of a share, as the case may be. For purposes of this Section 8, the number of shares of Common Stock deemed to be issued and outstanding as of a given date shall be the sum of the number of shares of Common Stock (excluding any treasury shares of the Corporation) issued and outstanding.

9. Miscellaneous.

(a) Amendments in Writing. Except as otherwise provided herein, the provisions of the Preferred Stock may be amended and the Corporation may take any action herein prohibited, or omit to perform any act herein required to be performed by it, only if the Corporation has obtained the written consent of the holders of a majority of the then outstanding shares of Preferred Stock.

***[Remainder of page intentionally left blank]***

**IN WITNESS WHEREOF**, the Corporation has caused this Certificate of Designations, Preferences and Rights to be signed in its name and on its behalf on this 30th day of September, 2023 by a duly authorized officer of the Corporation.

BLUE WATER BIOTECH, INC.

By: _____
Name: Erin Henderson
Title: Chief Business Officer

**ANNEX A**

NOTICE OF CONVERSION

(TO BE EXECUTED BY THE REGISTERED HOLDER IN ORDER TO CONVERT SHARES OF SERIES A CONVERTIBLE PREFERRED STOCK)

The undersigned hereby elects to convert the number of shares of Series A Convertible Preferred Stock ("Preferred Stock") indicated below into shares of common stock, par value $0.00001 per share (the "Common Stock"), of Blue Water Biotech, Inc., a Delaware corporation (the "Corporation"), according to the conditions hereof, as of the date written below. If shares of Common Stock are to be issued in the name of a person other than the undersigned, the undersigned will pay all transfer taxes payable with respect thereto and is delivering herewith such certificates and opinions as may be required by the Corporation. No fee will be charged to the undersigned for any conversion, except for any such transfer taxes.

Conversion calculations:

Date to Effect Conversion: _____

Number of shares of Preferred Stock owned prior to Conversion: _____

Number of shares of Preferred Stock to be Converted: _____

Stated Value of shares of Preferred Stock to be Converted: _____

Number of shares of Common Stock to be Issued: _____

Applicable Conversion Price:_____

Number of shares of Preferred Stock subsequent to Conversion: _____

Address for Delivery: _____
or
DWAC Instructions:
Broker no: _____
Account no: _____

[HOLDER]

By: _____
Name:
Title:

Exhibit C

**BLUE WATER BIOTECH, INC.**

**PROMISSORY NOTE**

$[2,300,000.00][3] October __, 2023

FOR VALUE RECEIVED, the undersigned, **BLUE WATER BIOTECH, INC.**, a Delaware corporation ("**Borrower**"), hereby promises to pay to [_____, a _____], or its designees or assigns ("**Holder**"), the principal sum of [Two Million Three Hundred Thousand Dollars ($2,300,000.00)] on the terms and conditions provided herein.

1. Asset Purchase Agreement. This Promissory Note (the "**Note**") is issued by Borrower, on the date hereof, pursuant to the Asset Purchase Agreement dated as of June 13, 2023 (as amended, restated, supplemented or otherwise modified, the "**Asset Purchase Agreement**"), by and among Borrower, WraSer, LLC, a Mississippi limited liability company and 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**"), and is subject to the terms thereof. Capitalized terms used herein and not defined herein have the meanings ascribed to such terms in the Asset Purchase Agreement.

2. Repayment; Prepayment.

(a) Except as otherwise provided herein, principal under this Note shall be payable as follows: (i) monthly installments of principal hereunder in the amount of [One Hundred Fifty Thousand and 00/100 Dollars ($150,000)] (or, if less, the then remaining principal outstanding hereunder) shall be payable monthly commencing on January 30, 2024 and continuing on the last business day of each calendar month thereafter; and (ii) the entire remaining principal hereunder shall be payable on April 30, 2025 (the "**Maturity Date**").

(b) Borrower shall have the right, at its option, at any time or from time to time prior to the Maturity Date, to prepay this Note, in whole or in part, without premium or penalty. Any prepayments of this Note shall be applied to the remaining installments of principal due hereunder in inverse order of maturity.

(c) Promptly (but in any event within one (1) Business Day) following a Change of Control (as defined below), Borrower shall prepay the entire remaining principal under this Note, plus all outstanding and unpaid fees and expenses and other amounts payable to Holder hereunder to the date of such prepayment. "**Change of Control**" means, with respect to Borrower: (i) the sale of all or substantially all of Borrower's assets; (ii) a merger, reorganization or consolidation involving Borrower in which the voting securities of Borrower outstanding immediately prior thereto cease to represent at least fifty percent (50%) of the combined voting power of the surviving entity immediately after such merger, reorganization, or consolidation; or (iii) a person or entity, or group of persons or entities acting in concert, acquire more than fifty percent (50%) of the voting equity securities or management control of Borrower.

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[3] Separate Note to be issued to each secured party under the Plexus Loan Agreement so the Note amount and Holder name will be updated accordingly for each.

(d) Upon the occurrence and during the continuance of any Event of Default (as defined below), upon written notice from Holder to Borrower all amounts outstanding under this Note shall bear interest from the date of the occurrence of such Event of Default until such Event of Default is cured or waived in writing at a rate equal to eight percent (8.0%) per annum, which interest shall be payable to Holder in cash on demand or, at Holder's option, payable in kind by adding such interest to the principal amount hereof.

(e) In the event that any interest rate(s) provided for in this Section 2 shall be determined to exceed any limitation on interest rates under applicable laws, such interest rate(s) shall be computed at the highest rate permitted by applicable laws. Any payment by Borrower of any interest amount in excess of that permitted by applicable law shall be considered a mistake, with the excess being applied to the outstanding principal amount of this Note without prepayment premium or penalty; if no such principal amount is outstanding, such excess shall be returned to Borrower.

3. Payments. All payments of principal and interest under this Note shall be made in currency of the United States and shall be made to Holder by wire transfer to an account designated by Holder or in such other manner as Holder may designate to Borrowers in writing. If any payment is scheduled to be due and payable on a day which is not a business day, such payment shall instead be due and payable on the immediately following business day. All payments in connection with this Note shall be applied first to any fees or expenses payable hereunder, second to accrued and unpaid interest, if any, and third to unpaid principal.

4. Representations and Warranties. Borrower represents and warrants to Holder as follows:

(a) Due Organization and Qualification. Borrower is a corporation duly organized, validly existing and in good standing under the laws of its state of organization.

(b) Due Authorization; No Conflict; Enforceability. The execution, delivery and performance of this Note are within Borrower's organizational powers, have been duly authorized, and do not constitute a breach of any provision contained in Borrower's organizational documents, nor will such execution, delivery or performance constitute an event of default under any material agreement by which Borrower is bound. This Note constitutes the legal, valid and binding obligation of Borrower, enforceable against Borrower in accordance with its terms, except as enforceability may be limited by applicable bankruptcy, insolvency, reorganization, moratorium and similar laws of general applicability relating to or affecting creditors' rights and by general principles of equity.

5. Events of Default; Remedies.

(a) An "Event of Default" shall occur hereunder upon the occurrence of any one or more of the following events:

(i) Borrower fails to pay the principal of this Note (or any installment thereof) as and when due hereunder (whether at scheduled maturity, upon acceleration or otherwise) or fails to pay within three (3) business days after the date due any interest, fees, expenses or other amounts payable to Holder hereunder;

(ii) any representation or warranty made or deemed made by or on behalf of Borrower to Holder under or in connection with this Note shall be materially false when made or deemed made;

(iii) Borrower fails to observe or perform, in any material respect, any other covenant or agreement on the part of Borrower contained in this Note which failure continues for a period of thirty (30) days after Borrower's receipt of written notice thereof from Holder;

(iv) Borrower makes a general assignment for the benefit of its creditors or applies to any tribunal for the appointment of a trustee or receiver of a substantial part of the assets of Borrower, or Borrower commences any proceedings relating to Borrower under any bankruptcy, reorganization, arrangement, insolvency, readjustment of debts, dissolution or other liquidation law of any jurisdiction; or any such application is filed, or any such proceedings are commenced against Borrower and Borrower indicates its consent to such proceedings, or an order or decree is entered by a court of competent jurisdiction appointing such trustee or receiver, or adjudicating Borrower bankrupt or insolvent, or approving the petition in any such proceedings, and such order or decree remains unstayed and in effect for sixty (60) days.

(b) Acceleration. If an Event of Default occurs under Section 5(a)(iv), then the outstanding principal of and interest on this Note shall automatically become immediately due and payable, without presentment, demand, protest or notice of any kind, all of which are expressly waived, and Holder shall be entitled to exercise all of its rights and remedies under this Note whether at law or in equity. If any other Event of Default occurs and is continuing, Holder, by written notice to Borrower, may declare the outstanding principal of and interest on this Note to be due and payable immediately. Upon any such declaration of acceleration, such principal and interest shall become immediately due and payable, without presentment, demand, protest or notice of any kind, all of which are expressly waived, and Holder shall be entitled to exercise all of its rights and remedies under this Note whether at law or in equity.

6. Amendment and Waiver. Any amendment, waiver, supplement or modification of or to any provision of this Note and any consent to any departure by any party from the terms of any provision of this Note, shall be effective (i) only if it is made or given in writing and signed by Borrower and Holder and (ii) only in the specific instance and for the specific purpose for which made or given. No failure or delay on the part of Holder in exercising any right, power or remedy hereunder shall operate as a waiver thereof, nor shall any single or partial exercise of any such right, power or remedy preclude any other or further exercise thereof or the exercise of any other right, power or remedy.

7. Suits for Enforcement. Upon the occurrence of any one or more Events of Default, Holder may, during the continuation thereof, proceed to protect and enforce its rights hereunder by suit in equity, action at law or by other appropriate proceeding, whether for the specific performance of any covenant or agreement contained in this Note or in aid of the exercise of any power granted in this Note, or may proceed to enforce the payment of this Note, or to enforce any other legal or equitable right of Holder under this Note.

8. Expenses. Borrower will pay all reasonable out-of-pocket expenses of Holder (including, without limitation, reasonable attorneys' fees and expenses) in connection with (a) any enforcement of this Note, and (b) any amendment or waiver of or to any provision of this Note.

9. Remedies Cumulative. No remedy conferred upon Holder herein is intended to be exclusive of any other remedy and each such remedy shall be cumulative and shall be in addition to every other remedy given hereunder, or now or hereafter existing at law or in equity or by statute or otherwise.

10. Transfer. Holder may transfer or assign this Note and its rights hereunder in whole or in part to one or more transferees. Upon any such transfer or assignment of this Note, Borrower shall, at its expense, execute and deliver one or more new notes of like tenor and of a like aggregate principal amount, registered in the name of Holder or its transferee(s).

11. Replacement of Note. On receipt by Borrower of an affidavit of an authorized representative of Holder stating the circumstances of the loss, theft, destruction or mutilation of this Note (and in the case of any such mutilation, on surrender and cancellation of such Note), Borrower, at its expense, will promptly execute and deliver, in lieu thereof, a new Note of like tenor.

12. Covenants Bind Successors and Assigns. All the covenants, stipulations, promises and agreements in this Note contained by or on behalf of Borrower shall bind its successors and assigns, whether so expressed or not; provided, however, that Borrower may not assign any of its rights, or any of its obligations, under this Note without the prior written consent of Holder, and any such purported assignment by Borrower without the written consent of Holder shall be void and of no effect.

13. Notices. All notices, demands and other communications provided for or permitted hereunder shall be made in writing and shall be by registered or certified first-class mail, return receipt requested, courier service or personal delivery:

(a) if to Holder:

_____
_____
Attention:_____

(b) if to Borrower:

_____
_____
Attention:_____

All such notices shall be deemed to have been duly given: when delivered by hand, if personally delivered; one business day after delivery by courier, if delivered by commercial overnight courier service; or if mailed, five business days after being deposited in the mail, postage prepaid.

14. GOVERNING LAW. THIS NOTE AND THE RIGHTS AND OBLIGATIONS OF THE PARTIES HEREUNDER SHALL BE GOVERNED BY, CONSTRUED IN ACCORDANCE WITH, AND ENFORCED UNDER, THE LAWS OF THE STATE OF NORTH CAROLINA, WITHOUT REGARD TO THE PRINCIPLES OF CONFLICTS OF LAW OF SUCH STATE THAT WOULD REQUIRE THE APPLICATION OF THE LAW OF ANOTHER JURISDICTION.

15. Jurisdiction, Jury Trial Waiver, Etc.

(a) EACH PARTY TO THIS NOTE HEREBY IRREVOCABLY AGREES THAT ANY LEGAL ACTION OR PROCEEDING ARISING OUT OF OR RELATING TO THIS NOTE MAY BE BROUGHT IN THE COURTS OF THE STATE OF NORTH CAROLINA OR OF THE UNITED STATES OF AMERICA FOR THE EASTERN DISTRICT OF NORTH CAROLINA AND HEREBY EXPRESSLY SUBMITS TO THE PERSONAL JURISDICTION AND VENUE OF SUCH COURTS FOR THE PURPOSES THEREOF AND EXPRESSLY WAIVES ANY CLAIM OF IMPROPER VENUE AND ANY CLAIM THAT ANY SUCH COURT IS AN INCONVENIENT FORUM. EACH PARTY HEREBY IRREVOCABLY CONSENTS TO THE SERVICE OF PROCESS OF ANY OF THE AFOREMENTIONED COURTS IN ANY SUCH SUIT, ACTION OR PROCEEDING BY THE MAILING OF COPIES THEREOF BY REGISTERED OR CERTIFIED MAIL, POSTAGE PREPAID, TO ITS ADDRESS SET FORTH IN SECTION 13, SUCH SERVICE TO BECOME EFFECTIVE 10 DAYS AFTER SUCH MAILING.

(b) TO THE EXTENT PERMITTED BY APPLICABLE LAW, EACH PARTY TO THIS NOTE HEREBY WAIVES ITS RIGHT TO A JURY TRIAL WITH RESPECT TO ANY ACTION OR CLAIM ARISING OUT OF ANY DISPUTE IN CONNECTION WITH THIS NOTE OR ANY RIGHTS OR OBLIGATIONS HEREUNDER OR THE PERFORMANCE OF SUCH RIGHTS AND OBLIGATIONS. BORROWER (i) CERTIFIES THAT NO REPRESENTATIVE, AGENT OR ATTORNEY OF HOLDER HAS REPRESENTED, EXPRESSLY OR OTHERWISE, THAT HOLDER WOULD NOT, IN THE EVENT OF LITIGATION, SEEK TO ENFORCE THE FOREGOING WAIVERS AND (ii) ACKNOWLEDGES THAT HOLDER HAS BEEN INDUCED TO ENTER INTO THIS NOTE BY, AMONG OTHER THINGS, THE WAIVERS AND CERTIFICATIONS CONTAINED HEREIN.

16. Severability. In case any provision in or obligation under this Note shall be invalid, illegal or unenforceable in any jurisdiction, the validity, legality and enforceability of the remaining provisions or obligations, or of such provision or obligation in any other jurisdictions, shall not in any way be affected or impaired thereby.

17. Waivers. All parties bound by this obligation, whether primarily or secondarily liable as principals, sureties, guarantors, endorsers or otherwise, hereby waive the benefits of all provisions of law for stay or delay or execution or sale of property or other satisfaction of judgment against any of them on account of liability hereon until judgment is obtained, executed and issued against any of them and in turn satisfied, or until it can be shown that Borrower or any other party hereto had no property available for satisfaction of the debt evidenced by this instrument, or until any other proceedings can be had against any of them. Demand, presentment, protest, notice of protest and notice of dishonor are hereby waived by all parties bound hereon.

18. Headings. The headings in this Note are for convenience of reference only and shall not limit or otherwise affect the meaning hereof.

19. Signatures/Counterparts. Electronic (pdf) transmissions of any executed original document and/or retransmission of any executed electronic (pdf) transmission shall be deemed to be the same as the delivery of an executed original. At the request of any party hereto, the other parties hereto shall confirm electronic (pdf) transmissions by executing duplicate original documents and delivering the same to the requesting party or parties. This Note may be executed in any number of counterparts and by the parties hereto in separate counterparts, each of which when so executed shall be deemed to be an original and all of which taken together shall constitute one and the same agreement.

[Signature Pages Follow]

In witness whereof, Borrowers has caused this Note to be executed as of the date first written above.

**BLUE WATER BIOTECH, INC.**

By: _____
Name:
Its:

ACKNOWLEDGED AND ACCEPTED:

By: _____
Name:
Title:

**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: October 20, 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: October 20, 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 June 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: October 20, 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 June 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: October 20, 2023

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