

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

FORM 10-Q

Quarterly report pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934

For the quarterly period ended September 30, 2024.

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 001-40023

GT BIOPHARMA, INC.

(Exact name of registrant as specified in its charter)

Delaware
(State or other jurisdiction of
incorporation or organization)

94-1620407
(I.R.S. Employer
Identification Number)

(Address not applicable¹)

415-919-4040
(Registrant's telephone number, including area code)

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

| Title of Each Class | Trading Symbol | Name of exchange on which registered |
|---|----------------|--------------------------------------|
| Common Stock, \$0.001 par value per share | GTBP | Nasdaq Capital Market |

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 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 is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes No

As of November 10, 2024, the registrant had 2,234,328 shares of common stock outstanding.

¹ Effective as of July 1, 2024, the Company became a fully remote company. We do not maintain a principal executive office. For purposes of compliance with applicable requirements of the Securities Act of 1933, as amended, and the Securities Exchange Act of 1934, as amended, any stockholder communication required to be sent to the Company's principal executive offices may be directed to 315 Montgomery Street, 10th Floor, San Francisco, California 94104, or by email to auditcommittee@gtbiopharma.com.

GT Biopharma, Inc. and Subsidiaries
FORM 10-Q
For the Nine Months Ended September 30, 2024
Table of Contents

| | <u>Page</u> |
|---|-------------|
| PART I FINANCIAL INFORMATION | |
| Item 1. Financial Statements | |
| Condensed Consolidated Balance Sheets as of September 30, 2024 (Unaudited) and December 31, 2023 | 3 |
| Condensed Consolidated Statements of Operations for the three and nine months ended September 30, 2024 and 2023 (Unaudited) | 4 |
| Condensed Consolidated Statements of Stockholders' Equity for the three and Condensed Consolidated Statements of Operations for the three and nine months ended September 30, 2024 and 2023 (Unaudited) | 5 |
| Condensed Consolidated Statements of Cash Flows for the Condensed Consolidated Statements of Operations for the nine months ended September 30, 2024 and 2023 (Unaudited) | 7 |
| Condensed Notes to Consolidated Financial Statements (Unaudited) | 8 |
| Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations | 20 |
| Item 3. Quantitative and Qualitative Disclosures About Market Risk | 28 |
| Item 4. Controls and Procedures | 28 |
| PART II OTHER INFORMATION | |
| Item 1. Legal Proceedings | 29 |
| Item 6. Exhibits | 30 |
| SIGNATURES | 31 |

GT BIOPHARMA, INC. AND SUBSIDIARIES
Condensed Consolidated Balance Sheets

| | September 30, 2024 | December 31, 2023 |
|---|---------------------------|--------------------------|
| | (Unaudited) | |
| ASSETS | | |
| Current assets | | |
| Cash and cash equivalents | \$ 6,418,000 | \$ 1,079,000 |
| Restricted cash | 93,000 | — |
| Short-term investments | — | 12,893,000 |
| Prepaid expenses and other current assets | 248,000 | 84,000 |
| Total Current Assets | 6,759,000 | 14,056,000 |
| Operating lease right-of-use asset | — | 53,000 |
| TOTAL ASSETS | \$ 6,759,000 | \$ 14,109,000 |
| LIABILITIES AND STOCKHOLDERS' EQUITY | | |
| Current liabilities | | |
| Accounts payable | \$ 2,612,000 | \$ 4,328,000 |
| Accrued expenses | 1,868,000 | 1,195,000 |
| Current operating lease liability | — | 58,000 |
| Warrant liability | 182,000 | 1,052,000 |
| Total Current Liabilities | 4,662,000 | 6,633,000 |
| Stockholders' Equity | | |
| Convertible Preferred stock, par value \$0.01, 15,000,000 shares authorized Series C - 96,230 shares issued and outstanding at September 30, 2024 and December 31, 2023, respectively | 1,000 | 1,000 |
| Common stock, par value \$0.001, 250,000,000 shares authorized, 2,234,328 and 1,380,633 shares issued and outstanding as of September 30, 2024 and December 31, 2023, respectively | 2,000 | 1,000 |
| Additional paid in capital | 693,546,000 | 689,539,000 |
| Accumulated deficit | (691,452,000) | (682,065,000) |
| Total Stockholders' Equity | 2,097,000 | 7,476,000 |
| TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY | \$ 6,759,000 | \$ 14,109,000 |

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

GT BIOPHARMA, INC. AND SUBSIDIARIES
Condensed Consolidated Statements of Operations

| | For The Three Months Ended September 30, | | For the Nine Months Ended September 30, | |
|--|---|-----------------------|--|-----------------------|
| | 2024 | 2023 | 2024 | 2023 |
| | (Unaudited) | (Unaudited) | (Unaudited) | (Unaudited) |
| Operating Expenses: | | | | |
| Research and development | \$ 1,307,000 | \$ 1,364,000 | \$ 3,868,000 | \$ 5,109,000 |
| Selling, general and administrative (including \$0 and \$547,000 from stock compensation granted to officers, directors, and employees and for services for the three months ended September 30, 2024 and 2023, respectively, and \$222,000 and \$1,767,000 for the nine months ended September 30, 2024 and 2023, respectively) | 2,297,000 | 1,758,000 | 6,733,000 | 5,299,000 |
| Loss from Operations | (3,604,000) | (3,122,000) | (10,601,000) | (10,408,000) |
| Other Income (Expense) | | | | |
| Interest income | 96,000 | 216,000 | 343,000 | 600,000 |
| Interest expense | — | — | — | (213,000) |
| Change in fair value of warrant liability | 95,000 | 485,000 | 870,000 | 4,796,000 |
| Gain on extinguishment of debt | — | — | — | 547,000 |
| Unrealized gain on marketable securities | 2,000 | 5,000 | 1,000 | 43,000 |
| Total Other Income, Net | 193,000 | 706,000 | 1,214,000 | 5,773,000 |
| Net Loss | \$ (3,411,000) | \$ (2,416,000) | \$ (9,387,000) | \$ (4,635,000) |
| Net Loss Per Share - Basic and Diluted | \$ (1.53) | \$ (1.77) | \$ (5.28) | \$ (3.47) |
| Weighted average common shares outstanding - basic and diluted | 2,234,328 | 1,367,206 | 1,777,313 | 1,336,532 |

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

GT BIOPHARMA, INC. AND SUBSIDIARIES
CONDENSED CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY
For The Three and Nine Months Ended September 30, 2024 (Unaudited):

| | Preferred Shares | | Common Shares | | Additional Paid in Capital | Accumulated Deficit | Total |
|-----------------------------|------------------|-----------------|------------------|-----------------|----------------------------------|-------------------------|---------------------|
| | Shares | Amount | Shares | Amount | | | |
| Balance, June 30, 2024 | 96,230 | \$ 1,000 | 2,234,328 | \$ 2,000 | \$ 693,546,000 | \$ (688,041,000) | \$ 5,508,000 |
| Net loss | - | - | - | - | - | (3,411,000) | (3,411,000) |
| Balance, September 30, 2024 | <u>96,230</u> | <u>\$ 1,000</u> | <u>2,234,328</u> | <u>\$ 2,000</u> | <u>\$ 693,546,000</u> | <u>\$ (691,452,000)</u> | <u>\$ 2,097,000</u> |

| | Preferred Shares | | Common Shares | | Additional Paid in Capital | Accumulated Deficit | Total |
|--|------------------|-----------------|------------------|-----------------|----------------------------------|-------------------------|---------------------|
| | Shares | Amount | Shares | Amount | | | |
| Balance, December 31, 2023 | 96,230 | \$ 1,000 | 1,380,633 | \$ 1,000 | \$ 689,539,000 | \$ (682,065,000) | \$ 7,476,000 |
| Issuance of common stock and warrants for cash | - | - | 740,000 | 1,000 | 2,975,000 | - | 2,976,000 |
| Cancellation of common stock issued to prior CFO | - | - | (13,902) | - | - | - | - |
| Issuance of common shares to settle vendor payable | - | - | 127,597 | - | 810,000 | - | 810,000 |
| Fair value of vested stock options | - | - | - | - | 222,000 | - | 222,000 |
| Net loss | - | - | - | - | - | (9,387,000) | (9,387,000) |
| Balance, September 30, 2024 | <u>96,230</u> | <u>\$ 1,000</u> | <u>2,234,328</u> | <u>\$ 2,000</u> | <u>\$ 693,546,000</u> | <u>\$ (691,452,000)</u> | <u>\$ 2,097,000</u> |

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

GT BIOPHARMA, INC. AND SUBSIDIARIES
CONDENSED CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY
For The Three and Nine Months Ended September 30, 2023 (Unaudited):

| | Preferred Shares | | Common Shares | | Additional Paid in Capital | Accumulated Deficit | Total |
|--|------------------|-----------------|------------------|-----------------|----------------------------------|-------------------------|----------------------|
| | Shares | Amount | Shares | Amount | | | |
| Balance, June 30, 2023 | 96,230 | \$ 1,000 | 1,354,656 | \$ 1,000 | \$ 688,448,000 | \$ (676,687,000) | \$ 11,763,000 |
| Issuance of common shares for services | - | - | 13,333 | 1,000 | 114,000 | - | 115,000 |
| Issuance of common shares to settle vendor payable | - | - | 12,644 | - | 110,000 | - | 110,000 |
| Fair value of vested stock options | - | - | - | - | 433,000 | - | 433,000 |
| Net loss | - | - | - | - | - | (2,416,000) | (2,416,000) |
| Balance, September 30, 2023 | <u>96,230</u> | <u>\$ 1,000</u> | <u>1,380,633</u> | <u>\$ 2,000</u> | <u>\$ 689,105,000</u> | <u>\$ (679,103,000)</u> | <u>\$ 10,005,000</u> |

| | Preferred Shares | | Common Shares | | Additional Paid in Capital | Accumulated Deficit | Total |
|---|------------------|-----------------|------------------|-----------------|----------------------------------|-------------------------|----------------------|
| | Shares | Amount | Shares | Amount | | | |
| Balance, December 31, 2022 | 96,230 | \$ 1,000 | 1,090,748 | \$ 1,000 | \$ 686,200,000 | \$ (674,467,000) | \$ 11,734,000 |
| Private placement of common stock | - | - | 120,000 | - | 6,268,000 | - | 6,268,000 |
| Issuance of common stock for exercise of prefunded warrants | - | - | 96,666 | - | - | - | - |
| Initial recognition of fair value of warrant liability | - | - | - | - | (5,831,000) | - | (5,831,000) |
| Issuance of common shares for services | - | - | 15,782 | 1,000 | 429,000 | - | 430,000 |
| Issuance of common shares to settle vendor payable | - | - | 57,437 | - | 701,000 | - | 701,000 |
| Fair value of vested stock options | - | - | - | - | 1,338,000 | - | 1,338,000 |
| Net loss | - | - | - | - | - | (4,635,000) | (4,635,000) |
| Balance, September 30, 2023 | <u>96,230</u> | <u>\$ 1,000</u> | <u>1,380,633</u> | <u>\$ 2,000</u> | <u>\$ 689,105,000</u> | <u>\$ (679,103,000)</u> | <u>\$ 10,005,000</u> |

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

GT BIOPHARMA, INC. AND SUBSIDIARIES
Condensed Consolidated Statements of Cash Flows

| | For The Nine Months Ended | |
|---|----------------------------------|--------------------|
| | September 30, | |
| | 2024 | 2023 |
| | (Unaudited) | (Unaudited) |
| CASH FLOWS FROM OPERATING ACTIVITIES | | |
| Net loss | \$ (9,387,000) | \$ (4,635,000) |
| Adjustments to reconcile net loss to net cash used in operating activities: | | |
| Stock based compensation – services | — | 430,000 |
| Stock based compensation - officers, directors, and employees | 222,000 | 1,337,000 |
| Change in fair value of warrant liability | (870,000) | (4,796,000) |
| Gain on extinguishment of share settled debt | — | (547,000) |
| Change in operating lease right-of-use assets | 53,000 | 78,000 |
| Unrealized loss (gain) on marketable securities | 1,000 | (43,000) |
| Changes in operating assets and liabilities: | | |
| Decrease in prepaid expenses | (164,000) | 16,000 |
| Increase (Decrease) in accounts payable and accrued expenses | (233,000) | 1,437,000 |
| (Decrease) in operating lease liability | (58,000) | (82,000) |
| Net Cash Used in Operating Activities | (10,436,000) | (6,805,000) |
| CASH FLOWS FROM INVESTING ACTIVITIES | | |
| Sale (Purchase) of investments | 12,892,000 | (2,487,000) |
| Net Cash Provided by (Used in) Investing Activities | 12,892,000 | (2,487,000) |
| CASH FLOWS FROM FINANCING ACTIVITIES | | |
| Proceeds from issuance of common stock and warrants, net | 2,976,000 | 6,268,000 |
| Net Cash Provided by Financing Activities | 2,976,000 | 6,268,000 |
| Net Increase (Decrease) in Cash and Cash Equivalents and Restricted Cash | 5,432,000 | (3,024,000) |
| Cash and Cash Equivalents and Restricted Cash at Beginning of Period | 1,079,000 | 5,672,000 |
| Cash and Cash Equivalents and Restricted Cash at End of Period | \$ 6,511,000 | \$ 2,648,000 |
| <u>SUPPLEMENTAL DISCLOSURES OF CASH FLOW INFORMATION:</u> | | |
| Cash paid during the year for: | | |
| Interest | \$ — | \$ — |
| Income taxes | \$ — | \$ — |
| <u>SUPPLEMENTAL DISCLOSURES OF NON-CASH INVESTING AND FINANCING ACTIVITIES</u> | | |
| Initial recognition of fair value of warrant liability | \$ — | \$ 5,831,000 |
| Fair value of common stock issued to a vendor to settle accounts payable | \$ 810,000 | \$ 700,000 |

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

GT BIOPHARMA, INC. AND SUBSIDIARIES
NOTES TO UNAUDITED CONDENSED CONSOLIDATED FINANCIAL STATEMENTS
Nine Months Ended September 30, 2024 and 2023 (Unaudited)

Note 1 – Organization and Going Concern Analysis

Organization

The corporate predecessor of GT Biopharma, Inc, Diagnostic Data, Inc., was incorporated in the state of California in 1965. Diagnostic Data, Inc. changed its incorporation to the state of Delaware on December 21, 1972 and changed its name to DDI Pharmaceuticals, Inc. on March 11, 1985. On September 7, 1994, DDI Pharmaceuticals, Inc. merged with International BioClinical, Inc. and Bioxytech S.A. and changed its name to OXIS International, Inc. On July 17, 2017, OXIS International, Inc. changed its name to GT Biopharma, Inc.

Throughout this Quarterly Report on Form 10-Q, the terms “GTBP,” “we,” “us,” “our,” “the Company” and “our Company” refer to GT Biopharma, Inc.

The GT Biopharma logo, TriKE®, and other trademarks or service marks of GT Biopharma, Inc. appearing in this quarterly report are the property of the Company. This quarterly report on Form 10-Q also contains registered marks, trademarks and trade names of other companies. All other trademarks, registered marks and trade names appearing herein are the property of their respective holders.

The Company is a clinical stage biopharmaceutical company focused on the development and commercialization of novel immune-oncology products based on our proprietary Tri-specific Killer Engager (TriKE®), and Tetra-specific Killer Engager (Dual Targeting TriKE®) platforms. The Company’s TriKE® and Dual Targeting TriKE® platforms generate proprietary therapeutics designed to harness and enhance the cancer killing abilities of a patient’s own natural killer cells (NK cells).

Going Concern Analysis

The accompanying unaudited condensed consolidated financial statements have been prepared assuming that the Company will continue as a going concern. The Company does not have any product candidates approved for sale and has not generated any revenue from its product sales. The Company has sustained operating losses since inception, and expects such losses to continue into the foreseeable future. Historically, the Company has financed its operations through public and private sales of common stock, issuance of preferred and common stock, issuance of convertible debt instruments, and strategic collaborations. For the nine months ended September 30, 2024, the Company recorded a net loss of approximately \$9.4 million and used cash in operations of approximately \$10.4 million. These factors raise substantial doubt about the Company’s ability to continue as a going concern within one year of the date that the financial statements are issued.

The unaudited condensed consolidated financial statements do not include any adjustments that might be necessary if the Company is unable to continue as a going concern. Accordingly, the unaudited condensed consolidated financial statements have been prepared on a basis that assumes the Company will continue as a going concern and which contemplates the realization of assets and satisfaction of liabilities and commitments in the ordinary course of business.

The Company has evaluated the significance of the uncertainty regarding the Company’s financial condition in relation to its ability to meet its obligations, which has raised substantial doubt about the Company’s ability to continue as a going concern. While it is very difficult to estimate the Company’s future liquidity requirements, the Company believes if it is unable to obtain additional financing, existing cash resources will not be sufficient to enable it to fund the anticipated level of operations through one year from the date the accompanying unaudited condensed consolidated financial statements are issued. There can be no assurances that the Company will be able to secure additional financing on acceptable terms. In the event the Company does not secure additional financing, the Company will be forced to delay, reduce, or eliminate some or all of its discretionary spending, which could adversely affect the Company’s business prospects, ability to meet long-term liquidity needs and the ability to continue operations.

Note 2 – Summary of Significant Accounting Policies

Basis of Presentation and Principles of Consolidation

The condensed consolidated financial statements include the accounts of the Company and its wholly-owned subsidiaries, Oxis Biotech, Inc. and Georgetown Translational Pharmaceuticals, Inc. All intercompany transactions and balances have been eliminated in consolidation.

The accompanying condensed consolidated financial statements are unaudited. These unaudited interim condensed consolidated financial statements have been prepared in accordance with accounting principles generally accepted in the United States of America (“GAAP”) and applicable rules and regulations of the Securities and Exchange Commission (“SEC”) regarding interim financial reporting. Certain information and note disclosures normally included in the financial statements prepared in accordance with GAAP have been condensed or omitted pursuant to such rules and regulations. Accordingly, these interim condensed consolidated financial statements should be read in conjunction with the consolidated financial statements and notes thereto contained in the Company’s Annual Report on Form 10-K for the fiscal year ended December 31, 2023 filed with the SEC on March 26, 2024 (the “2023 Annual Report”). The consolidated balance sheet as of December 31, 2023 included herein, was derived from the audited consolidated financial statements as of that date.

In the opinion of management, the accompanying unaudited condensed consolidated financial statements contain all adjustments necessary to fairly present the Company’s financial position and results of operations for the interim periods reflected. Except as noted, all adjustments contained herein are of a normal recurring nature. Results of operations for the fiscal periods presented herein are not necessarily indicative of fiscal year-end results.

Accounting Estimates

The preparation of financial statements in conformity with 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 revenues and expenses during the reporting period. Actual results could differ from those estimates. Significant estimates include management’s estimates for continued liquidity, accruals for potential liabilities, assumptions used in deriving the fair value of derivative liabilities, valuation of equity instruments issued for debt and services and realization of deferred tax assets.

Cash Equivalents and Short-Term Investments

The Company considers highly liquid investments with maturities of three months or less at the date of acquisition as cash equivalents in the accompanying unaudited condensed consolidated financial statements. At September 30, 2024 total cash equivalents which consist of money market funds and US treasuries, amounted to approximately \$6.2 million. At December 31, 2023 total cash equivalents which consist of money market funds, amounted to approximately \$443,000.

Management generally determines the appropriate classification of its investments at the time of purchase. We classify these investments as short-term investments, as part of current assets, based upon our ability and intent to use any and all of these investments as necessary to satisfy liquidity requirements that may arise from our business. Investments are carried at fair value with the unrealized holding gains and losses reported in the accompanying unaudited condensed consolidated statements of operations. At September 30, 2024 and December 31, 2023, total short-term investments which consist of US treasuries and US government agencies, amounted to approximately \$0 and \$12.9 million, respectively.

Restricted Cash

As of September 30, 2024, the Company has classified certain cash balances as restricted cash in its unaudited condensed consolidated balance sheets. The Company’s restricted cash is deposited in a financial institution and held as a collateral for a credit card agreement with the same financial institution.

Fair Value of Financial Instruments

Financial Accounting Standards Board (“FASB”) Accounting Standards Codification (“ASC”) 820-10 requires entities to disclose the fair value of financial instruments, both assets and liabilities recognized and not recognized on the balance sheet for which it is practicable to estimate fair value. ASC 820-10 defines the fair value of a financial instrument as the amount at which the instrument could be exchanged in a current transaction between willing parties.

The three levels of the fair value hierarchy are as follows:

Level 1 Valuations based on unadjusted quoted prices in active markets for identical assets or liabilities that the entity has the ability to access.

Level 2 Valuations based on quoted prices for similar assets or liabilities, quoted prices in markets that are not active, or other inputs that are observable or can be corroborated by observable data for substantially the full term of the assets or liabilities.

Level 3 Valuations based on inputs that are unobservable, supported by little or no market activity and that are significant to the fair value of the assets or liabilities.

The carrying amounts of the Company's other financial assets and liabilities, such as cash and cash equivalents, short term investments, prepaid expenses and other current assets, accounts payable, accrued expenses, approximate their fair values because of the short maturity of these instruments.

The carrying amount of the Company's warrant liability of \$182,000 and \$1.1 million at September 30, 2024 and December 31, 2023, respectively, was based on Level 3 measurements.

Warrant Liability

The Company evaluates its financial instruments to determine if such instruments are derivatives or contain features that qualify as embedded derivatives in accordance with ASC Topic 815, "*Derivatives and Hedging*" ("ASC 815"). For derivative financial instruments that are accounted for as liabilities, the derivative instrument is initially recorded at its fair value and is then re-valued at each reporting date, with changes in the fair value reported in the statements of operations.

The Company's use of derivative financial instruments is generally limited to warrants issued by the Company that do not meet the criteria for equity treatment and are recorded as liabilities. We do not use financial instruments or derivatives for any trading purposes.

Common Stock (February 2024 Reverse Stock Split)

On February 2, 2024, the Company effectuated a reverse stock-split of its common stock, par value \$0.001 per share, at a ratio of 1 for 30. The Company's common stock began trading on a reverse stock-split-adjusted basis on The Nasdaq Capital Market on February 5, 2024 under the existing trading symbol "GTBP."

As a result of the reverse stock-split, every thirty (30) shares of issued and outstanding common stock were automatically combined into one issued and outstanding share of common stock, without any change in the par value per share. No fractional shares will be issued in connection with the reverse stock split. Stockholders who otherwise would be entitled to receive fractional shares of common stock will be entitled to receive their pro-rata portion of the net proceeds obtained from the aggregation and sale by the exchange agent of the fractional shares resulting from the reverse stock-split (reduced by any customary brokerage fees, commission and other expenses). The reverse stock split reduced the number of shares of common stock outstanding on the effective date of the reverse stock-split from 41,419,000 shares to 1,380,633 shares, subject to minor adjustments due to the treatment of fractional shares. The number of authorized shares of common stock remains unchanged at 250,000,000 shares.

Proportionate adjustments have been made to the per share exercise price and the number of shares of common stock that may be purchased upon exercise of outstanding stock options and warrants for the Company's common stock, and to the number of shares of common stock reserved for future issuance pursuant to the Company's 2022 Omnibus Incentive Plan.

All share and per share information within this report have been adjusted to retroactively reflect the reverse stock-split as of the earliest period presented.

Stock-Based Compensation

The Company periodically issues stock-based compensation to officers, directors, employees, and consultants for services rendered. Such issuances vest and expire according to terms established at the issuance date.

Stock-based payments to officers, directors, employees, and consultants in exchange for goods and services, which include grants of employee stock options, are recognized in the financial statements based on their grant date fair values in accordance with ASC 718, *Compensation-Stock Compensation*. Stock based payments to officers, directors, employees, and consultants, which are generally time vested, are measured at the grant date fair value and depending on the conditions associated with the vesting of the award, compensation cost is recognized on a straight-line or graded basis over the vesting period. Recognition of compensation expense for non-employees is in the same period and manner as if the Company had paid cash for the services. The fair value of stock options granted is estimated using the Black-Scholes option-pricing model, which uses certain assumptions related to risk-free interest rates, expected volatility, expected life, and future dividends. The assumptions used in the Black-Scholes option pricing model could materially affect compensation expense recorded in future periods.

Research and Development Expenses

Costs incurred for research and development are expensed as incurred. The salaries, benefits, and overhead costs of personnel conducting research and development of the Company's products are included in research and development expenses. Purchased materials that do not have an alternative future use are also expensed.

Leases

The Company accounts for its lease in accordance with the guidance of ASC 842, *Leases*. The Company determines whether a contract is, or contains, a lease at inception. Right-of-use assets represent the Company's right to use an underlying asset during the lease term, and lease liabilities represent the Company's obligation to make lease payments arising from the lease. Right-of-use assets and lease liabilities are recognized at lease commencement based upon the estimated present value of unpaid lease payments over the lease term. The Company uses its incremental borrowing rate based on the information available at lease commencement in determining the present value of unpaid lease payments.

In June 2024, the Company's lease expired and was not renewed.

Net Loss Per Share

Basic earnings (loss) per share is computed using the weighted-average number of common shares outstanding during the period. Diluted earnings (loss) per share is computed using the weighted-average number of common shares and the dilutive effect of contingent shares outstanding during the period. Potentially dilutive contingent shares, which primarily consist of stock issuable upon exercise of stock options and warrants have been excluded from the diluted loss per share calculation because their effect is anti-dilutive.

The following common stock equivalents were excluded in the computation of the net loss per share because their effect is anti-dilutive:

| | September 30, 2024 (Unaudited) | September 30, 2023 (Unaudited) |
|-----------------------------------|-----------------------------------|-----------------------------------|
| Options to purchase common stock | 101,264 | 124,599 |
| Warrants to purchase common stock | 1,133,762 | 304,962 |
| Total anti-dilutive securities | 1,235,026 | 429,561 |

Concentration

Cash is deposited in one financial institution. The balances held at this financial institution at times may be in excess of Federal Deposit Insurance Corporation ("FDIC") insurance limits of up to \$250,000. Management believes that the financial institutions that hold the Company's cash are financially sound and, accordingly, minimal credit risk exists.

The Company has a significant concentration of expenses incurred from and accounts payable and accrued expenses to Cytovance, a related party, and the University of Minnesota, see Note 4 – Accounts Payable and Related Party.

Segments

The Company determined its reporting units in accordance with "*Segment Reporting*" ("ASC 280"). Management evaluates a reporting unit by first identifying its operating segments under ASC 280. The Company then evaluates each operating segment to determine if it includes one or more components that constitute a business. If there are components within an operating segment that meet the definition of a business, the Company evaluates those components to determine if they must be aggregated into one or more reporting units. If applicable, when determining if it is appropriate to aggregate different operating segments, the Company determines if the segments are economically similar and, if so, the operating segments are aggregated.

Management has determined that the Company has one consolidated operating segment. The Company's reporting segment reflects the manner in which its chief operating decision maker reviews results and allocates resources. The Company's reporting segment meets the definition of an operating segment and does not include the aggregation of multiple operating segments. As a result no further segment information is presented in these consolidated financial statements.

Recent Accounting Pronouncements

In November 2023, the FASB issued ASU No. 2023-07, "*Segment Reporting (Topic 280): Improvements to Reportable Segment Disclosures*" ("ASU 2023-07"), which introduces new reportable segment disclosure requirements related to significant segment expenses and also expands reportable segment disclosure requirements for interim reporting. The amendment will require public entities to disclose significant segment expenses that are regularly provided to the chief operating decision maker and are included within each reportable segment's profits and losses. This standard became effective for the Company on January 1, 2024. The adoption of this standard did not have a material impact on the Company's results of operations, financial position or cash flows.

The Company's management has evaluated all the recently issued, but not yet effective, accounting standards and guidance that have been issued or proposed by the FASB or other standards-setting bodies through the filing date of these financial statements and does not believe the future adoption of any such pronouncements will have a material effect on the Company's financial position and results of operations.

Note 3 – Fair Value of Financial Instruments

Financial Assets

The following table represents the estimated fair values of the Company’s financial instruments:

| | September 30, 2024 (Unaudited) | | | |
|------------------------|--------------------------------|------------------|-------------------|------------|
| | Cost | Unrealized Gains | Unrealized Losses | Fair Value |
| Short-term investments | \$ — | \$ — | \$ — | \$ — |
| Total | \$ — | \$ — | \$ — | \$ — |

| | December 31, 2023 | | | |
|------------------------|-------------------|------------------|-------------------|---------------|
| | Cost | Unrealized Gains | Unrealized Losses | Fair Value |
| Short-term investments | \$ 12,845,000 | \$ 48,000 | \$ — | \$ 12,893,000 |
| Total | \$ 12,845,000 | \$ 48,000 | \$ — | \$ 12,893,000 |

The following table represents the Company’s fair value hierarchy for its financial assets (cash equivalents and investments):

| | September 30, 2024 (Unaudited) | | | |
|-------------------------|--------------------------------|--------------|--------------|---------|
| | Fair Value | Level 1 | Level 2 | Level 3 |
| Cash equivalents: | | | | |
| Money market funds | \$ 1,220,000 | \$ 1,220,000 | \$ — | \$ — |
| US treasuries | 4,987,000 | — | 4,987,000 | — |
| Short-term investments: | | | | |
| US treasuries | — | — | — | — |
| Total financial assets | \$ 6,207,000 | \$ 1,220,000 | \$ 4,987,000 | \$ — |

| | December 31, 2023 | | | |
|--------------------------------------|-------------------|------------|---------------|---------|
| | Fair Value | Level 1 | Level 2 | Level 3 |
| Cash equivalents: | | | | |
| Money market funds | \$ 443,000 | \$ 443,000 | \$ — | \$ — |
| Short-term investments: | | | | |
| US treasuries and US gov’t. agencies | 12,893,000 | — | 12,893,000 | — |
| Total financial assets | \$ 13,336,000 | \$ 443,000 | \$ 12,893,000 | \$ — |

Warrant Liability

For the details of warrant liability transactions see Note 5 – Warrant Liability.

Note 4 – Accounts Payable and Related Party

Accounts payable consists of the following:

| | As of September 30, 2024 (Unaudited) | As of December 31, 2023 |
|---|--|----------------------------|
| Accounts payable to Cytovance, a related party ¹ | \$ 638,000 | \$ 3,515,000 |
| Accounts payable to University of Minnesota | 697,000 | 130,000 |
| Other accounts payable | 1,277,000 | 683,000 |
| Total accounts payable | \$ 2,612,000 | \$ 4,328,000 |

¹Accounts Payable to Cytovance Biologics, Inc. (“Cytovance”), a Related Party, since Cytovance owns greater than 5% of the Company’s issued and outstanding common stock

See Note 8 – Commitments and Contingencies, Significant Agreements.

The details of the Company’s accounts payable to Cytovance Biologics, Inc., were as follows:

| | Nine Months Ending | |
|---|-----------------------------------|-----------------------------------|
| | September 30, 2024 (Unaudited) | September 30, 2023 (Unaudited) |
| Beginning balance | \$ 3,515,000 | \$ 2,283,000 |
| Invoices, net | 1,365,000 | 3,691,000 |
| Payments in cash | (3,432,000) | (1,710,000) |
| Payments in common stock, at fair value | (810,000) | (1,120,000) |
| Ending balance | <u>\$ 638,000</u> | <u>\$ 3,144,000</u> |

University of Minnesota

See Note 8 – Commitments and Contingencies, Significant Agreements.

Note 5 – Warrant Liability

2023 Warrants

On January 4, 2023, as part of the private placement offering, the Company issued common stock, warrants to purchase up to an aggregate of 216,667 shares of the Company’s common stock (the “2023 Common Warrants”), and placement agent warrants to purchase up to 13,000 shares of the Company’s common stock (the “2023 Placement Agents Warrants”).

The 2023 Common Warrants and the 2023 Placement Agents Warrants (collectively the “2023 Warrants”), provide for a value calculation for the warrants using the Black Scholes model in the event of certain fundamental transactions. The fair value calculation provides for a floor on the volatility amount utilized in the value calculation at 100% or greater. The Company has determined this provision introduces leverage to the holders that could result in a value that would be greater than the settlement amount of a fixed-for-fixed option on the Company’s own equity shares. Therefore, pursuant to ASC 815, the Company has classified the 2023 Warrants as a liability in its consolidated balance sheet. The classification of the 2023 Warrants, including whether they should be recorded as liability or as equity, is evaluated at the end of each reporting period.

The 2023 Warrants were initially recorded at a fair value at \$5.8 million at the grant date, and upon the closing of placement, was recorded as a cost of capital. The fair value of the 2023 Warrants classified as a liability in the Company’s unaudited condensed consolidated balance sheets and will be re-measured at the end of every reporting period with the change in value reported in the unaudited condensed consolidated statements of operations until they are either exercised or expired.

The 2023 Warrant liability is valued using a Binomial pricing model with the following assumptions:

| | 2023 Warrants | |
|---------------------------------------|-----------------------------------|----------------------------------|
| | September 30, 2024 (Unaudited) | December 31, 2023 (Unaudited) |
| Stock price | \$ 2.31 | \$ 7.20 |
| Risk-free interest rate ¹ | 3.58% | 4.6% |
| Expected volatility ² | 114% | 119.7% |
| Expected life (in years) ³ | 3.25 – 3.75 | 4.5 |
| Expected dividend yield ⁴ | — | — |
| Fair value of warrants | <u>\$ 182,000</u> | <u>\$ 1,051,000</u> |

¹Based on rates established by the Federal Reserve Bank

²Historical volatility of the Company’s common stock is used to estimate the future volatility of its common stock

³Determined by the remaining contractual life of the derivative instrument

⁴Based on no dividends paid or expected to be paid

2020 Warrants

The Company issued warrants underlying 58,824 shares of common stock during the year ended December 31, 2020 (the “2020 Warrants”), that contained a fundamental transaction provision that could give rise to an obligation to pay cash to the warrant holder upon occurrence of certain change in control type events. In accordance with ASC 480, the fair value of the 2020 Warrants is classified as a liability in the Company’s unaudited condensed consolidated balance sheets and will be re-measured at the end of every reporting period with the change in value reported in the unaudited condensed consolidated statements of operations until they are either exercised or expire.

The 2020 Warrant liability is valued using a Binomial pricing model with the following assumptions:

| | 2020 Warrants | |
|---------------------------------------|-----------------------------------|--------------------|
| | September 30, 2024 (Unaudited) | September 30, 2023 |
| Stock price | \$ 2.31 | \$ 7.20 |
| Risk-free interest rate ¹ | 3.98% | 5.0% |
| Expected volatility ² | 114% | 89.0% |
| Expected life (in years) ³ | 0.8 | 1.8 |
| Expected dividend yield ⁴ | — | — |
| Fair value of warrants | \$ — | \$ 2,000 |

Warrant Liability

The details of warrant liability transactions were as follows:

| | Nine Months Ending | |
|------------------------------------|-----------------------------------|-----------------------------------|
| | September 30, 2024 (Unaudited) | September 30, 2023 (Unaudited) |
| Beginning balance | \$ 1,052,000 | \$ 18,000 |
| Issuance of warrants at fair value | — | 5,831,000 |
| Change in fair value | (870,000) | (4,796,000) |
| Extinguishment | — | — |
| Ending balance | \$ 182,000 | \$ 1,053,000 |

Note 6 – Stockholders’ Equity

The Company’s authorized capital as of September 30, 2024 was 250,000,000 shares of common stock, par value \$0.001 per share, and 15,000,000 shares of preferred stock, par value \$0.01 per share.

Common Stock

2024 Common Stock Offering

On May 23, 2024, the Company received gross proceeds of approximately \$3.2 million, before deducting placement agent fees and other offering expenses of \$243,000 in relation to a purchase agreement (the “Purchase Agreement”) signed on May 21, 2024, between the Company and institutional investors (the “Purchasers”) for the issuance and sale, in a registered direct offering, of 740,000 shares of the Company’s common stock, par value \$0.001 per share (the “2024 Shares”). In a concurrent private placement, the Company issued and sold to the Purchasers warrants to purchase 740,000 shares of the Company’s common stock (the “2024 Common Warrants”). In addition, the Company issued warrants to the placement agent to purchase 88,800 shares of common stock (the “2024 Placement Agents Warrants”). The 2024 Common Warrants have an exercise price equal to \$4.35 per share, and the 2024 Placement Agents Warrants have an exercise price equal to \$5.4375 per share, both are exercisable commencing six months following issuance, and have a term of exercise equal to five years following the initial exercise date. The 2024 Shares and 2024 Common Warrants were sold at an offering price of \$4.35 per share and accompanying 2024 Common Warrant.

Pursuant to the Purchase Agreement, the Company agreed, with certain exceptions, for a period of 60 days following the closing of the offering not to issue, enter into an agreement to issue or announce the issuance or proposed issuance of the 2024 Shares or any other securities convertible into, or exercisable or exchangeable for, shares of the Company’s common stock. The Company has also agreed for a period of one year following the closing date of the offering not to (i) issue or agree to issue equity or debt securities convertible into, or exercisable or exchangeable for, shares at a conversion price, exercise price or exchange price which floats with the trading price of the 2024 Shares or which may be adjusted after issuance upon the occurrence of certain events or (ii) enter into any agreement, including an equity line of credit, whereby the Company may issue securities at a future-determined price.

The Company determined that under ASC 815-40, the 2024 Common Warrants and the 2024 Placement Agent Warrants do not contain a clause that adjusts the exercise price based on circumstances not considered to be within the Company's control and are considered indexed to the Company's own stock and eligible for an exception from derivative accounting. Accordingly, the fair value of the 2024 Common Warrants and the 2024 Placement Agent Warrants are classified as equity.

2023 Private Placement of Common Stock

On January 4, 2023, the Company received gross proceeds of \$6.5 million, before deducting placement agent fees and other offering expenses of \$232,000 in relation to a purchase agreement signed on December 30, 2022, between the Company and an institutional investor for the issuance and sale, in a registered direct offering, of 120,000 shares of the Company's common stock, par value \$0.001 per share (the "2023 Shares"), pre-funded warrants to purchase up to 96,667 shares of the Company's common stock (the "Pre-Funded Warrants"), warrants to purchase up to an aggregate of 216,667 shares of the Company's common stock (the "2023 Common Warrants") and placement agent warrants to purchase up to 13,000 of the Company's common stock (the "2023 Placement Agents Warrants"). The 2023 Common Warrants have an exercise price equal to \$30.00 per share, are exercisable commencing six months following issuance, and have a term of exercise equal to five years following the initial issuance date. The Pre-Funded Warrants had an exercise price of \$0.003 per share, are immediately exercisable and could be exercised at any time after their original issuance until such Pre-Funded Warrants were exercised in full. The 2023 Placement Agents Warrants have an exercise price equal to \$37.50 per share, are exercisable commencing six months following issuance, and have a term of exercise equal to five years following the initial issuance date. The 2023 Shares and 2023 Common Warrants were sold at an offering price of \$30.00 per share and accompanying 2023 Common Warrant and the Pre-Funded Warrants and 2023 Common Warrants were sold at an offering price of \$29.997 per Pre-Funded Warrant and accompanying 2023 Common Warrant.

The 2023 Common Warrants and the 2023 Placement Agents Warrants contained a clause not considered to be within the Company's control. The Company determined that the provision represented a variable that is not an input to the fair value of a "fixed-for-fixed" option as defined under ASC 815-40, and thus the 2023 Common Warrants and the 2023 Placement Agent Warrants are not considered indexed to the Company's own stock and not eligible for an exception from derivative accounting. Accordingly, the 2023 Common Warrants and the 2023 Placement Agent Warrants were classified as a warrant liability, and \$5.8 million of the initial common stock offering was classified as a warrant liability (see Note 5 – Warrant Liability).

Common Stock Issued for Services

During the nine months ended September 30, 2023, the Company issued 15,782 shares of common stock with a fair value of \$430,000 to members of the Company's Board of Directors (the "Board"), employees, and consultants. The shares were valued at the respective date of the agreements.

Preferred Stock

Series C Preferred Stock

As of September 30, 2024 and December 31, 2023, there were 96,230 shares of series C preferred stock, par value \$0.01 per share (the "Series C Preferred Stock") issued and outstanding.

As a result of reverse stock splits in previous years and the agreement terms for adjusting the rights of the related shares, the 96,230 shares of Series C Preferred Stock are not currently convertible, have no voting rights, and in the event of liquidation, the holders of the Series C Preferred Stock would not participate in any distribution of the assets or surplus funds of the Company. The holders of Series C Preferred Stock also are not currently entitled to any dividends if and when declared by the Board. No dividends to holders of the Series C Preferred Stock were declared or unpaid through September 30, 2024 and 2023, respectively.

Series K Preferred Stock

On February 16, 2021, the Board designated 115,000 shares of Series K preferred stock, par value \$.01 (the "Series K Preferred Stock").

Shares of the Series K Preferred Stock are convertible at any time, at the option of the holders, into shares of the Company's common stock at an effective conversion rate of 100 shares of common stock for each share of Series K Preferred. Shares of the Series K Preferred Stock have the same voting rights as the shares of the Company's common stock, with the holders of the Series K Preferred Stock entitled to vote on an as-converted-to-common stock basis, subject to the beneficial ownership limitation, together with the holders of the Company's common stock on all matters presented to the Company's stockholders. The Series K Preferred Stock are not entitled to any dividends (unless specifically declared by the Board) but will participate on an as-converted-to-common-stock basis in any dividends to the holders of the Company's common stock. In the event of the Company's dissolution, liquidation or winding up, the holders of the Series K Preferred Stock will be on parity with the holders of the Company's common stock and will participate, on a on an as-converted-to-common stock basis, in any distribution to holders of the Company's common stock.

As of September 30, 2024 and December 31, 2023, there were no shares of Series K Preferred stock issued and outstanding.

Note 7 – Common Stock Warrants and Options

Common Stock Warrants

Stock warrant transactions for the six months ended September 30, 2024 were as follows:

| | Nine Months Ended September 30, 2024 | |
|--|--------------------------------------|---------------------------------|
| | Number of Warrants | Weighted Average Exercise Price |
| Warrants outstanding at December 31, 2023 | 304,962 | \$ 63.30 |
| Granted | 828,800 | 4.47 |
| Forfeited/cancelled | — | — |
| Exercised | — | — |
| Warrants outstanding at September 30, 2024 | 1,133,762 | \$ 20.57 |
| Warrants exercisable at September 30, 2024 | 1,133,762 | \$ 20.57 |

As of September 30, 2024, all outstanding warrants are fully vested and had an exercise price greater than the market price of the Company's common stock, which resulted in no intrinsic value.

Warrants outstanding as of September 30, 2024 are exercisable as follows:

| Warrants Outstanding and Exercisable as of September 30, 2024 | | | | |
|---|--------------------|------------------------------------|----|---------------------------------|
| Range of Exercise Price | Number Outstanding | Weighted Average | | Weighted Average Exercise Price |
| | | Remaining Contractual Life (Years) | | |
| \$ 4.35 | 740,000 | 4.7 | \$ | 4.35 |
| 5.4375 | 88,800 | 4.6 | | 5.4375 |
| 30.00 | 216,666 | 3.8 | | 30.00 |
| 37.50 | 13,000 | 3.3 | | 37.50 |
| 102.00 | 1,867 | 0.8 | | 102.00 |
| 165.00 | 65,649 | 1.4 | | 165.00 |
| 206.25 | 7,780 | 1.4 | | 206.25 |
| | 1,133,762 | 4.2 | | 20.57 |

Common Stock Options

In April 2022 the Company established the 2022 Omnibus Incentive Plan (the "Plan"). The Plan was approved by our Board and stockholders. The purpose of the Plan is to grant stock and options to purchase our common stock, and other incentive awards, to our employees, directors, and key consultants. The maximum number of shares of common stock that may be issued pursuant to awards granted under the Plan is 166,667. The shares of our common stock underlying cancelled and forfeited awards issued under the Plan may again become available for grant under the Plan. As of September 30, 2024, there were 39,467 shares available for grant under the Plan.

The following table summarizes stock option transactions for the nine months ended September 30, 2024:

| | Nine Months Ended September 30, 2024 | |
|---|--------------------------------------|---------------------------------|
| | Number of Options | Weighted Average Exercise Price |
| Options outstanding at December 31, 2023 | 126,265 | \$ 40.15 |
| Granted | — | — |
| Forfeited/cancelled | (25,001) | 14.80 |
| Exercised | — | — |
| Options outstanding at September 30, 2024 | 101,264 | \$ 39.74 |
| Options exercisable at September 30, 2024 | 101,264 | \$ 39.74 |

The weighted average remaining contractual life of all options outstanding, and all options vested and exercisable as of September 30, 2024 was 8.2 years. Furthermore, all options outstanding and all options vested and exercisable as of September 30, 2024 had an exercise price greater than the market price of the Company's common stock, which resulted in no intrinsic value.

The total fair value of options that vested during the nine months ended September 30, 2024 and 2023, was \$222,000 and \$1,338,000, respectively, and is included in selling, general and administrative expense in the accompanying unaudited condensed consolidated statements of operations. As of September 30, 2024, all outstanding stock options were fully vested and exercisable and there was no unvested compensation expense.

On May 15, 2023, the Company granted stock options to a member of the Board to purchase 16,666 shares of common stock. The stock options are exercisable at \$10.50 per share, expire in 10 years, vest over twelve months and have a fair value of \$150,000 on at the date of grant which will be amortized over the vesting period.

On January 27, 2023, the Company granted stock options to employees and members of the Board to purchase an aggregate of 66,667 shares of common stock. The stock options are exercisable at \$25.50 per share, expire in 10 years, vest over twelve months and have a fair value of \$1.4 million at the date of grant which will be amortized over the vesting period.

Options outstanding as of September 30, 2024 are exercisable as follows:

| Stock Options Outstanding and Exercisable as of September 30, 2024 | | | | | |
|---|--------------------|---|---|-----------------------|--|
| Range of Exercise Price | Number | | Weighted Average | | Weighted Average Exercise Price |
| | Outstanding | Remaining Contractual Life (Years) | Remaining Contractual Life (Years) | Exercise Price | |
| \$ 10.50 | 16,666 | 8.6 | \$ | 10.50 | |
| 25.50 | 50,000 | 8.3 | | 25.50 | |
| 74.40 | 34,598 | 7.8 | | 74.40 | |
| | <u>101,264</u> | | | | |

Note 8 – Commitments and Contingencies

Litigation

The Company is involved in certain legal proceedings that arise from time to time in the ordinary course of our business. Except for income tax contingencies, we record accruals for contingencies to the extent that our management concludes that the occurrence is probable and that the related amounts of loss can be reasonably estimated. Legal expenses associated with the contingency are expensed as incurred. There is no current or pending litigation of any significance with the exception of the matters identified below that have arisen under, and are being handled in, the normal course of business:

Ohri Matter

On July 22, 2024, the Company filed an AAA Arbitration Demand against Manu Ohri, its former Chief Financial Officer. In the Demand, the Company asserts claims against Mr. Ohri for breach of his fiduciary duties and breach of contract and seeks a declaratory judgment providing that the Company may characterize Mr. Ohri's termination as "for cause" under his Employment Agreement, and that the Company may revoke the Separation Agreement entered into between the Company and Mr. Ohri prior to the Company learning of Mr. Ohri's breaches. In addition to the declaratory judgment, the Company seeks damages arising from Mr. Ohri's violations, and attorneys' fees and any forum and arbitration fees. On September 3, 2024, Mr. Ohri filed both a general denial of the Company's claims against him and counterclaims for breach of his Employment Agreement and Separation Agreement. At this early stage in the proceedings the Company is not able to determine the probability of the outcome of this matter or a range of reasonably expected losses, if any.

Berk Matter

On November 14, 2023, former interim Chief Executive Officer, Dr. Gregory Berk filed a lawsuit in the US District Court for the District of Massachusetts alleging that the Company discriminated and retaliated against Dr. Berk for engaging in protected whistleblowing activity in violation of the Sarbanes Oxley Act ("SOX"). The Company vigorously defended this matter and believes it to be without merit; however, the parties have agreed to resolve the matter and the Company expects the lawsuit to be dismissed shortly. The Company believes it has recorded appropriate accruals for the matter.

TWF Global Matter

On May 24, 2023, TWF Global, LLC (“TWF”) filed a Complaint in the California Superior Court for the County of Los Angeles naming the Company as defendant. The Complaint alleges that TWF is the holder of two Convertible Promissory Notes (“Notes”) and that the Company did not deliver shares of common stock due on conversion in February 2021. TWF was seeking per diem liquidated damages based on the terms of alleged Notes. On July 14, 2023, the Company filed a motion to dismiss for improper forum because the terms of the Notes, as alleged, require disputes to be filed in New York state and federal courts. TWF voluntarily dismissed its Complaint before the California Superior Court of Los Angeles without prejudice. The Company subsequently filed a Summons and Complaint for Interpleader against TWF and Z-One LLC before the Supreme Court of the State of New York County of New York, asking the Supreme Court to determine if the Company’s shares of common stock are properly registered to TWF or Z-One LLC, as both of these entities have made conflicting demands for registration of the shares of common stock. On February 5, 2024, the Company filed a motion for entry of default against TWF, seeking an order directing the Company to register the shares of common stock in the name of Z-One and that the Company be released from all associated liability and claims. The Court denied the motion without prejudice and will reconsider the motion without further briefing upon the filing of a supplemental party affidavit. On May 9, 2024, Z-One filed a motion for summary judgement seeking dismissal of the action, representing that Z-One and TWF have settled their dispute over the entitlement to the Company’s shares of common stock and there is no remaining dispute before the Court. On May 21, 2024, the Company filed a supplemental affidavit in support of its motion for entry of default. The Court has set a hearing on Z-One’s motion for November 14, 2024. The Company believes that any claims related to the Notes are without merit and will continue to defend vigorously against these claims.

Significant Agreements

Cytovance Biologics, Inc., a Related Party

In October 2020, the Company entered into a Master Services Agreement with Cytovance Biologics, Inc. (“Cytovance”), to perform biologic development and manufacturing services, and to produce and test compounds used in the Company’s potential product candidates. The Company subsequently executed numerous Statements of Work (“SOWs”) for the research and development of products for use in clinical trials.

On August 24, 2022, the Company entered into a Settlement and Investment Agreement with Cytovance that amended existing SOWs and allowed for future invoices to be settled in a combination of cash and issuance of the Company’s common stock. The Agreement also set Cytovance’s beneficial ownership limitation at 4.9% of the issued and outstanding shares of the Company’s common stock.

On April 25, 2024, the Company entered into an Amendment to the Settlement and Investment Agreement with Cytovance that increased Cytovance’s beneficial ownership limitation to 9.9% of the issued and outstanding shares of the Company’s common stock.

During the nine months ended September 30, 2024 and 2023, the Company recognized research and development expenses of \$1,365,000 and \$3,691,000, respectively and made cash payments amounting to \$3,432,000 and \$1,710,000, respectively to Cytovance. In addition, the Company issued 127,597 and 57,437 shares of common stock to Cytovance to settle accounts payable valued at approximately \$810,000 and \$1,120,000, respectively.

On June 30, 2024, Cytovance became a related party as their beneficial ownership exceeded 5% of the issued and outstanding shares of the Company’s common stock.

As of September 30, 2024 the Company’s commitments in relation to unbilled and unaccrued SOWs and any related Change Orders from Cytovance for services that have not yet been rendered as of September 30, 2024, amounted to approximately \$1.3 million.

University of Minnesota

2021 Scientific Research Agreement

Effective June 16, 2021, the Company entered into a scientific research agreement with the Regents of the University of Minnesota, expiring on June 30, 2023. Payments totaling approximately \$2.1 million are due over the life of the agreement. The purpose of the agreement is for the Regents of the University of Minnesota to continue work with the Company with three major goals in mind: (1) support the Company’s TriKE[®] product development and GMP manufacturing efforts; (2) TriKE[®] pharmacokinetics optimization in humans; and (3) investigation of the patient’s native NK cell population based on insights obtained from the analysis of the human data generated during our GTB-3550 clinical trial. The major deliverables proposed are: (1) creation of IND enabling data for TriKE[®] constructs in support of our product development and GMP manufacturing efforts; (2) TriKE[®] platform drug delivery changes to allow transition to alternative drug delivery means and extended PK in humans; and (3) gain an increased understanding of changes in the patient’s native NK cell population as a result of TriKE[®] therapy. Most studies will use TriKE[®] DNA/amino acid sequences created by the Company under existing licensing terms.

The Company recorded an expense classified as research and development of approximately \$0 and \$192,000, pursuant to the 2021 Scientific Research Agreement, for the nine months ended September 30, 2024 and 2023, respectively.

As of September 30, 2024 the Company’s commitments in relation to unbilled and unaccrued amounts from the University of Minnesota pursuant to the 2021 Scientific Research Agreement for services that have not yet been rendered as of September 30, 2024, amounted to \$0.

2023 Sponsored Research Agreement

On May 20, 2024, the Company entered into a sponsored research agreement with the Regents of the University of Minnesota (the “2016 Exclusive Patent License Agreement”), effective July 1, 2023, and expiring on July 1, 2025. Payments totaling approximately \$1.7 million are due over the life of the agreement. The purpose of the agreement is for the Regents of the University of Minnesota to continue work with the Company with three major goals in mind: (1) support the Company’s TriKE[®] product development and commercial GMP manufacturing efforts; (2) TriKE[®] pharmacokinetics optimization in humans and investigation of effects of altering the route of administration; and (3) research and development of TriKE[®] platform. The major deliverables proposed are: (1) creation of IND enabling data for TriKE[®] constructs in support of the Company’s product development and commercial GMP manufacturing efforts outside of the University of Minnesota; (2) TriKE[®] platform drug delivery changes to allow transition from intravenous (IV) continuous infusion to alternative drug delivery administration (IV bolus, intraperitoneal [IP], subcutaneous [SQ]) and extended PK in humans and gain an increased understanding of changes in the patient’s native NK cell population as a result of alteration of TriKE[®] administration; and (3) research and development of TriKE[®] platform combination with other FDA approved (or soon to be approved) therapeutics and alterations to TriKE[®] platform through formation of immune complexes. Most studies will use TriKE[®] DNA/amino acid sequences created by the Company under existing licensing terms.

The Company recorded an expense classified as research and development of approximately \$863,000 and \$0, pursuant to the 2023 Sponsored Research Agreement, for the nine months ended September 30, 2024 and 2023, respectively.

As of September 30, 2024 the Company’s commitments in relation to unbilled and unaccrued amounts from the University of Minnesota pursuant to the 2023 Sponsored Research Agreement for services that have not yet been rendered as of September 30, 2024, amounted to approximately \$862,000.

2016 Exclusive Patent License Agreement

Effective July 18, 2016, the Company entered into an exclusive patent license agreement with the Regents of the University of Minnesota (as amended, the “2016 Exclusive Patent License Agreement”), to further develop and commercialize cancer therapies using TriKE[®] technology developed by researchers at the University of Minnesota to target NK cells to cancer. Under the terms of the agreement, the Company receives exclusive rights to conduct research and to develop, make, use, sell, and import TriKE[®] technology worldwide for the treatment of any disease, state, or condition in humans. The Company is responsible for obtaining all permits, licenses, authorizations, registrations, and regulatory approvals required or granted by any governmental authority anywhere in the world that is responsible for the regulation of products such as the TriKE[®] technology, including without limitation the FDA and the European Agency for the Evaluation of Medicinal Products in the European Union. The agreement requires an upfront payment of \$200,000, and license maintenance fees of \$200,000 for years 2017 through 2020, and \$100,000 per year beginning in year 2021 and each year thereafter. The agreement also includes 4% royalty fees on the net sales of licensed products, not to exceed 6% under subsequent license agreements or amendments to this agreement, and minimum royalty payments due upon the commencement of commercial sales of licensed product is \$250,000 beginning in 2022, \$2 million beginning in 2025, and \$5 million beginning in 2027 throughout the remainder of the term. The agreement also includes numerous performance milestone payments including clinical development milestone payments totaling \$3.1 million, and one-time sales milestone payments of \$1 million upon reaching \$250 million in cumulative gross sales, and \$5 million upon reaching \$500 million in cumulative gross sales of licensed products.

Effective May 13, 2024, the Company entered into an amended and restated exclusive patent license agreement with the Regents of the University of Minnesota. The amendment requires an upfront payment of \$145,000 and amends the license maintenance fees to \$50,000 in 2025, and \$100,000 per year beginning in year 2026 and each year thereafter. The amendment also includes 1% to 5% royalty fees on the net sales of licensed products, not to exceed 6% under subsequent license agreements or amendments, and minimum royalty payments due upon the commencement of commercial sales of licensed product is \$250,000 in year one, \$2 million in years two through five, and \$5 million in year six throughout the remainder of the term. The amendment also includes numerous performance milestone payments including clinical development milestone payments totaling \$3.1 million, and one-time sales milestone, and one-time sales milestone payments of \$1 million upon reaching \$250 million in cumulative gross sales, and \$5 million upon reaching \$500 million in cumulative gross sales of licensed products.

The Company recorded an expense classified as research and development of \$145,000 and \$0, pursuant to the 2016 Exclusive Patent License Agreement, for the nine months ended September 30, 2024 and 2023, respectively.

2021 Exclusive License Agreement

Effective March 26, 2021, the Company entered into an exclusive license agreement with the Regents of the University of Minnesota (the “2021 Exclusive Patent License Agreement”), specific to the B7H3 targeted TriKE[®]. The agreement requires an upfront payment of \$20,000, and license maintenance fees of \$5,000 per year beginning in year 2022 and each year thereafter. The agreement also includes 2.5% to 5% royalty fees on the net sales of licensed products, and minimum royalty payments due upon the commencement of commercial sales of licensed product is \$250,000 in year one through four, and \$2 million beginning in year five and throughout the remainder of the term. The agreement also includes numerous performance milestone payments including clinical development milestone payments totaling \$3.1 million, and one-time sales milestone payments of \$1 million upon reaching \$250 million in cumulative gross sales, and \$5 million upon reaching \$500 million in cumulative gross sales of licensed products. There is no double payment intended; if one of the milestone payments has been paid under the 2016 restated exclusive patent license agreement no further payment is due for the corresponding milestone.

The Company did not incur any expenses pursuant to the 2021 Exclusive License Agreement, for the nine months ended September 30, 2024 and 2023, respectively.

Note 9 – Subsequent Events

On October 17, 2024, the Company granted stock options to an officer to purchase an aggregate of 23,335 shares of common stock. The stock options are exercisable at \$2.11 per share, expire in 10 years, vest over three years and have a fair value of approximately \$45,000 at the date of grant which will be amortized over the vesting period.

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

CAUTIONARY NOTICE REGARDING FORWARD-LOOKING STATEMENTS

Some of the statements in this Quarterly Report on Form 10-Q are “forward-looking statements” within the meaning of the safe harbor from liability established by the Private Securities Litigation Reform Act of 1995. Forward-looking statements include statements regarding our current beliefs, goals and expectations about matters such as our expected financial position and operating results, our business strategy and our financing plans. The forward-looking statements in this report are not based on historical facts, but rather reflect the current expectations of our management concerning future results and events. The forward-looking statements generally can be identified by the use of terms such as “believe,” “expect,” “anticipate,” “intend,” “plan,” “foresee,” “may,” “guidance,” “estimate,” “potential,” “outlook,” “target,” “forecast,” “likely” or other similar words or phrases. Similarly, statements that describe our objectives, plans or goals are, or may be, forward-looking statements. Forward-looking statements involve known and unknown risks, uncertainties and other factors that may cause our actual results, performance or achievements to be different from any future results, performance and achievements expressed or implied by these statements. We cannot guarantee that our forward-looking statements will turn out to be correct or that our beliefs and goals will not change. Our actual results could be very different from and worse than our expectations for various reasons. You should carefully review all information, including the discussion of risk factors under “Part I. Item 1A: Risk Factors” and “Part II. Item 7: Management’s Discussion and Analysis of Financial Condition and Results of Operations” of the Form 10-K for the year ended December 31, 2023. Any forward-looking statements in the Form 10-Q are made only as of the date hereof and, except as may be required by law, we do not have any obligation to publicly update any forward-looking statements contained in this Form 10-Q to reflect subsequent events or circumstances.

Organization

The corporate predecessor of GT Biopharma, Inc, Diagnostic Data, Inc., was incorporated in the state of California in 1965. Diagnostic Data, Inc. changed its incorporation to the state of Delaware on December 21, 1972 and changed its name to DDI Pharmaceuticals, Inc. on March 11, 1985. On September 7, 1994, DDI Pharmaceuticals, Inc. merged with International BioClinical, Inc. and Bioxytech S.A. and changed its name to OXIS International, Inc. On July 17, 2017, OXIS International, Inc. changed its name to GT Biopharma, Inc.

Overview

We are a clinical stage biopharmaceutical company focused on the development and commercialization of novel immuno-oncology products based on our proprietary Tri-specific Killer Engager (TriKE[®]), and Tetra-specific Killer Engager (Dual Targeting TriKE[®]) fusion protein immune cell engager technology platforms. Our TriKE[®] and Dual Targeting TriKE[®] platforms generates proprietary therapeutics designed to harness and enhance the cancer killing abilities of a patient’s own natural killer cells, or NK cells. Once bound to an NK cell, our moieties are designed to enhance the NK cell, and precisely direct it to one or more specifically targeted proteins expressed on a specific type of cancer cell or virus infected cell, resulting in the targeted cell’s death. TriKE[®]s can be designed to target any number of tumor antigens on hematologic malignancies or solid tumors and do not require patient-specific customization.

We are using our TriKE[®] platform with the intent to bring to market immuno-oncology products that can treat a range of hematologic malignancies, solid tumors, and potentially autoimmune disorders. The platform is scalable, and we are putting processes in place to be able to produce investigational new drug (IND) ready moieties in a timely manner after a specific TriKE[®] conceptual design. Specific drug candidates can then be advanced into the clinic on our own or through potential collaborations with partnering companies. We believe our TriKE[®]s may have the ability, if approved for marketing, to be used as both monotherapy and in combination with other standard-of-care therapies.

Our initial work was conducted in collaboration with the Masonic Cancer Center at the University of Minnesota under a program led by Dr. Jeffrey Miller, Professor of Medicine, and the Deputy Director at the Center. Dr. Miller is a recognized key opinion leader in the field of NK cell and IL-15 biology and their therapeutic potential. We have exclusive rights to the TriKE[®] platform and are generating additional intellectual property for specific moieties.

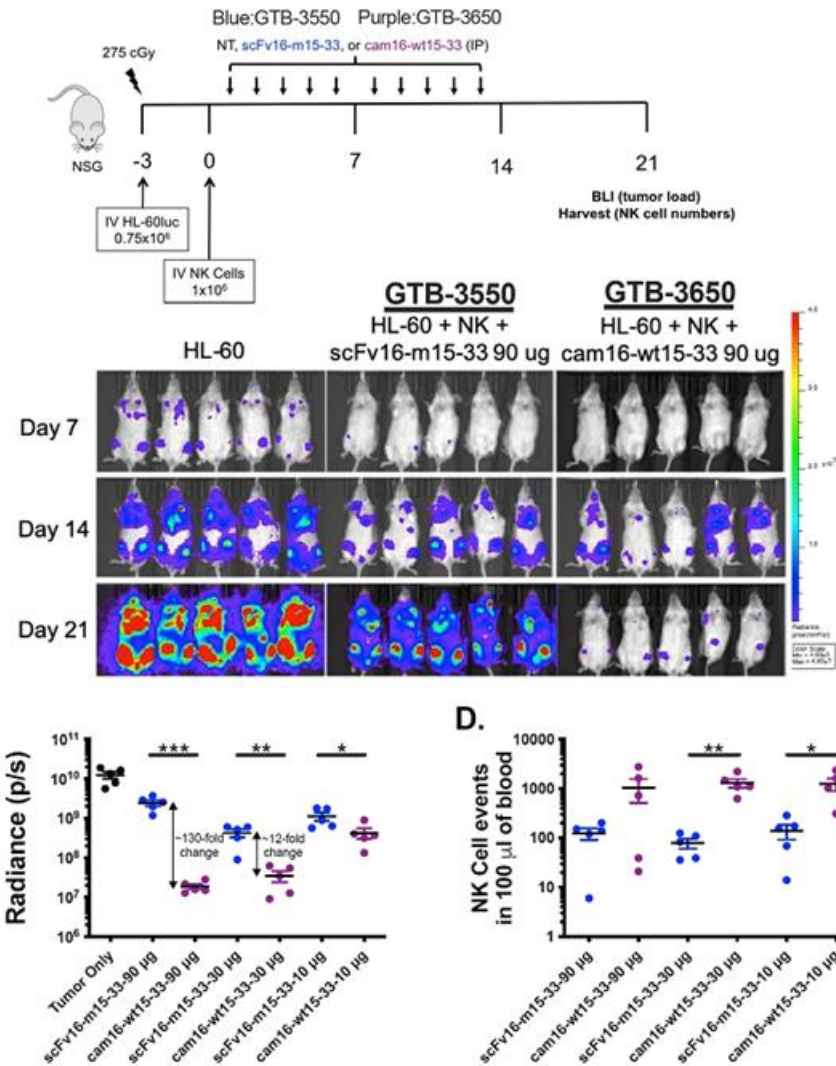
Our product pipeline as of September 30, 2024 is presented below:

| TriKE® Product Candidates | Approach | Target | Indication | Pre-Clinical | IND-Enabling/ GMP Manufacturing | Phase 1 | Phase 2 |
|---|-------------------------------|--------|------------------------------------|--------------|------------------------------------|---------|---|
| GTB-3550 | Monotherapy | CD33 | Leukemia – AML, MDS | | | | GTB-3550 supplanted by second generation nanobody GTB-3650 |
| GTB-3650 2nd Generation Camelid | Monotherapy | CD33 | Leukemia – AML, MDS | | | | |
| | Combination with Chemotherapy | CD33 | Leukemia – AML, MDS | | | | GTB-3650 Phase 1 trail initiation expected H2 2024 |
| GTB-5550 | Monotherapy & Combination | B7H3 | Solid Tumors | | | | GTB-5550 IND submission expected H1 2025 |
| GTB-6550 | Monotherapy & Combination | HER2 | Solid Tumors | | | | |
| GTB-7550 | Monotherapy & Combination | CD19 | B-Cell Malignancies | | | | |
| GTB-1050 | Monotherapy & Combination | | HIV | | | | |
| Undisclosed Candidates | Monotherapy & Combination | | Solid & Hematological Malignancies | | | | |

GTB-3550

GTB-3550 was our first TriKE® product candidate. It reflected our first-generation TriKE® platform. It is a single-chain, tri-specific scFv recombinant fusion protein conjugate composed of the variable regions of the heavy and light chains of anti-CD16 and anti-CD33 antibodies and a modified form of IL-15. We studied this anti-CD16-IL-15-anti-CD33 TriKE® in CD33 positive leukemias, a marker expressed on tumor cells in acute myelogenous leukemia, or AML, and myelodysplastic syndrome, or MDS. CD33 is primarily a myeloid differentiation antigen with endocytic properties broadly expressed on AML blasts and, possibly, some leukemic stem cells. CD33 or Siglec-3 (sialic acid binding Ig-like lectin 3, SIGLEC3, SIGLEC3, gp67, p67) is a transmembrane receptor expressed on cells of myeloid lineage. It is usually considered myeloid-specific, but it can also be found on some lymphoid cells. The anti-CD33 antibody fragment used for these studies was derived from the M195 humanized anti-CD33 scFv and has been used in multiple human clinical studies. It has been exploited as a target for therapeutic antibodies for many years. We believe the approval of the antibody-drug conjugate gemtuzumab validates this targeted approach.

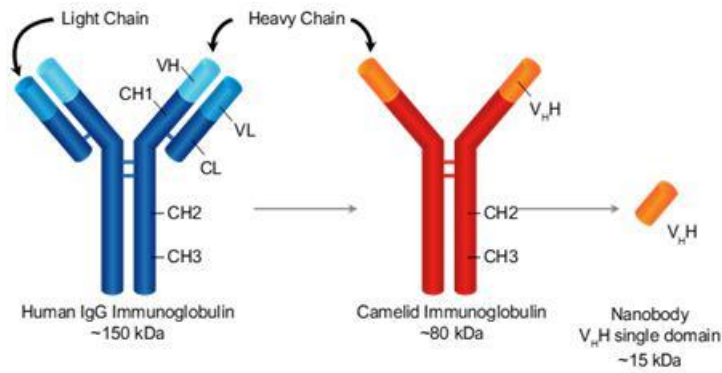
GTB-3550 was replaced by a more potent next-generation camelid nanobody TriKE®, GTB-3650, both targeting CD33 on relapsed/refractory AML and high-risk MDS. The pivot from GTB-3550 to GTB-3650 in our clinical development was based on a solid preclinical foundation that showed markedly enhanced potency of the camelid modification of the first-generation TriKE®. This is illustrated below by better tumor control of AML bearing animals with GTB-3650 (purple dots) compared to GTB-3550 (blue dots). This provided the rationale for pausing further development of GTB-3550 and moving over to solely develop the second-generation TriKE® platform.



Second Generation TriKE[®]s Utilize Camelid Nanobody Technology

Our goal is to be a leader in immuno-oncology therapies targeting a broad range of indications including hematological malignancies and solid tumors. A key element of our strategy includes introducing a next-generation camelid nanobody platform. Camelid antibodies (often referred as nanobodies) are smaller than human immunoglobulin and consist of two heavy chains. These nanobodies have the potential to have greater affinity to target antigens, potentially resulting in greater potency. We are utilizing this camelid antibody structure for all of our new TriKE[®] product candidates.

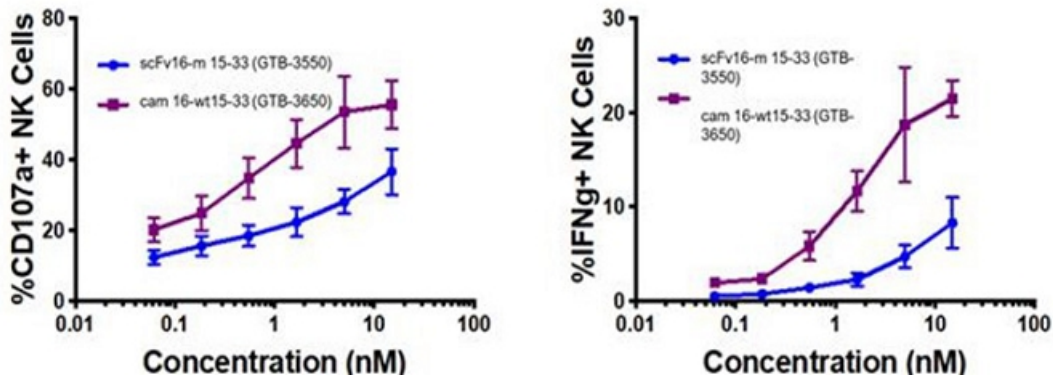
To develop second generation TriKE[®]s, we designed a new humanized CD16 engager derived from a single-domain antibody. While scFvs consist of a heavy and a light variable chain joined by a linker, single-domain antibodies consist of a single variable heavy chain capable of engaging without the need of a light chain counterpart (see figure below).



These single-domain antibodies are thought to have certain attractive features for antibody engineering, including physical stability, ability to bind deep grooves, and increased production yields, amongst others. Pre-clinical studies demonstrated increased NK cell activation against CD33+ targets including enhanced NK cell degranulation (% CD107a+) and IFN γ with the single-domain CD16 TriKE[®] (cam 16-wt15-33; GTB-3650) compared to the original TriKE[®] (scFv16-m 15-33; GTB-3550) (see figure below). This data was published by Dr. Felices M et al (2020) in Cancer Immunol Res.

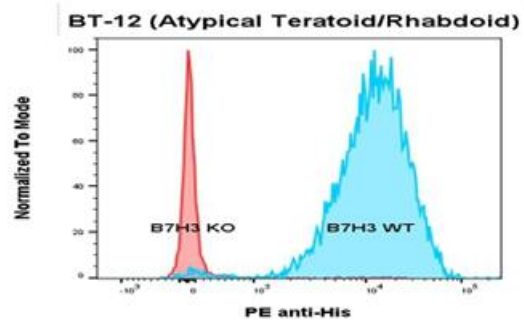
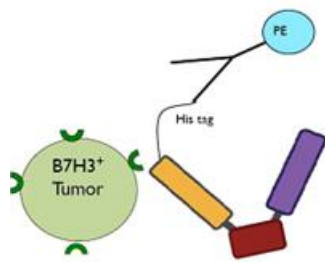
CD33+ HL60 Targets in Killing Assays

The purple line represents the GTB-3650 and the blue line represents GTB-3550.



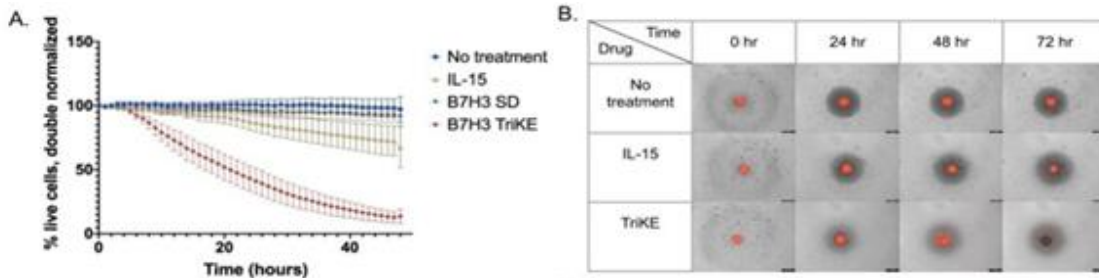
GTB-3650

GTB-3650 is a CD33 targeted TriKE[®] which targets CD33 on the surface of myeloid leukemias and an agonistic camelid engager to the potent activating receptor on NK cells, CD16. Use of this engager enhances the activity of wild type IL-15 included in GTB-3650, no longer needing the mutant IL-15 included in GTB-3550. The TriKE[®] approach provides a novel way to specifically target these tumors by leveraging NK cells, which have been shown to mediate relapse protection in this setting, in an anti-CD33-targeted fashion. We are moving GTB-3650 clinically based on pre-clinical data showing a marked increase in potency compared to GTB-3550, which we anticipate could lead to an enhanced efficacy signal in AML and MDS. We have advanced GTB-3650 through preclinical studies and filed an Investigational New Drug (IND) application with the U.S. Food and Drug Administration (FDA) in December 2023. In late June 2024, we received clearance from the FDA with respect to our IND Application in relation to GTB 3650. We further anticipate approval to start study enrollment targeting patients with relapsed/refractory AML and high grade MDS in the second half of 2024. This initial study will test GTB-3650 as monotherapy testing administration 2 weeks on and two weeks off (to prevent NK cell exhaustion) for at least 2 cycles of therapy. The design of the trial has been agreed on with the FDA.



GTB-5550

GTB-5550 is a B7-H3 targeted TriKE® which targets B7-H3 on the surface of advanced solid tumors (figure above). B7-H3 is an exciting target as it displays specific expression on a broad spectrum of solid tumor malignancies, allowing our team to target these malignancies through GTB-5550. Pre-clinical work has shown that this molecule has NK-cell targeted activity against a variety of solid tumor settings, including head and neck cancer squamous cell carcinoma (figure below), prostate cancer, breast cancer, ovarian cancer, glioblastoma, and lung cancer (amongst others). We are advancing GTB-5550 through preclinical studies and initiated a GMP manufacturing campaign in anticipation of filing an IND in the first half of 2025. A pre-IND packet was submitted to the FDA in October 2023 with a written response from the FDA in December 2023. The main question from the FDA was regarding pre-clinical toxicology and a pivot to subcutaneous dosing. The initial trial expected in 2025 is designed as a basket trial for patients with B7-H3+ solid tumors using Monday through Friday dosing (2 weeks on and 2 weeks off to prevent immune exhaustion), and is dependent on manufacturing of clinical materials.



GTB-7550

GTB-7550 TriKE® is a product candidate in development for the treatment of lupus and other autoimmune disorders. GTB-7550 TriKE® is a tri-specific molecule composed of a camelid nanobody that binds the CD16 receptor on NK cells, a scFv engager against CD19 on malignant and normal B cells, and a human IL-15 sequence between them.

Critical Accounting Policies and Estimates

The preparation of our consolidated financial statements in conformity with accounting principles generally accepted in the United States, or GAAP, requires us to make estimates and assumptions that affect the reported amounts of assets, liabilities, revenue and expenses, and related disclosure of contingent assets and liabilities. When making these estimates and assumptions, we consider our historical experience, our knowledge of economic and market factors and various other factors that we believe to be reasonable under the circumstances. Actual results may differ under different estimates and assumptions. The accounting estimates and assumptions discussed in this section are those that we consider to be the most critical to gain an understanding of our financial statements because they inherently involve significant judgments and uncertainties.

Use of Estimates

The preparation of financial statements in conformity with 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 revenues and expenses during the reporting period. Significant estimates include accruals for potential liabilities, assumptions used in deriving the fair value of warrant liabilities, valuation of equity instruments issued for services, and valuation of deferred tax assets. Actual results could differ from those estimates.

Warrant Liability

We evaluate our financial instruments to determine if such instruments are derivatives or contain features that qualify as embedded derivatives in accordance with ASC Topic 815, "Derivatives and Hedging". For derivative financial instruments that are accounted for as liabilities, the derivative instrument is initially recorded at its fair value and is then re-valued at each reporting date, with changes in the fair value reported in the statements of operations.

Our use of derivative financial instruments is generally limited to warrants issued by us that do not meet the criteria for equity treatment and are recorded as liabilities. We do not use financial instruments or derivatives for any trading purposes.

Stock-Based Compensation

We periodically issue stock-based compensation to officers, directors, employees, and consultants for services rendered. Such issuances vest and expire according to terms established at the issuance date.

Stock-based payments made to officers, directors, employees, and consultants in exchange for goods and services, including grants of employee stock options, are recognized in the financial statements based on their grant date fair values in accordance with ASC 718, *Compensation-Stock Compensation*. Stock based payments to officers, directors, employees, and consultants, which are generally time vested, are measured at the grant date fair value and depending on the conditions associated with the vesting of the award, compensation cost is recognized on a straight-line or graded basis over the vesting period. Recognition of compensation expense for non-employees is in the same period and manner as if we had paid cash for the services. The fair value of stock options granted is estimated using the Black-Scholes option-pricing model, which uses certain assumptions related to risk-free interest rates, expected volatility, expected life, and future dividends. The assumptions used in the Black-Scholes option pricing model could materially affect compensation expense recorded in future periods.

Results of Operations

Comparison of the Three and Nine Months Ended September 30, 2024 and 2023

Operating Expenses

| | Three Months Ended September 30, | | | |
|-------------------------------------|----------------------------------|---------------------|-------------------|------------|
| | 2024 | 2023 | \$ Change | % Change |
| Operating Expenses: | | | | |
| Research and development | \$ 1,307,000 | \$ 1,364,000 | \$ (57,000) | (4)% |
| Selling, general and administrative | 2,297,000 | 1,211,000 | 1,086,000 | 90% |
| Stock compensation | — | 547,000 | (547,000) | (100)% |
| Total Operating Expenses | <u>\$ 3,604,000</u> | <u>\$ 3,122,000</u> | <u>\$ 482,000</u> | <u>15%</u> |

| | Nine Months Ended September 30, | | | |
|-------------------------------------|---------------------------------|----------------------|-------------------|-----------|
| | 2024 | 2023 | \$ Change | % Change |
| Operating Expenses: | | | | |
| Research and development | \$ 3,868,000 | \$ 5,109,000 | \$ (1,241,000) | (24)% |
| Selling, general and administrative | 6,511,000 | 3,532,000 | 2,979,000 | 84% |
| Stock compensation | 222,000 | 1,767,000 | (1,545,000) | (87)% |
| Total Operating Expenses | <u>\$ 10,601,000</u> | <u>\$ 10,408,000</u> | <u>\$ 193,000</u> | <u>2%</u> |

Research and Development Expenses

Research and development expenses decreased by \$57,000 and approximately \$1.2 million, for the three and nine months ended September 30, 2024 and 2023, respectively, primarily due to a decrease in project materials costs, partially offset by an increase in scientific research costs.

Research and development expenses relate to our continued development and production of our most advanced TriKE® product candidates GTB-3650 and GTB-5550 along with the progression on other promising candidates. In late June 2024, we received clearance from the FDA with respect to our IND Application in relation to GTB 3650. We anticipate our direct clinical and preclinical expenses to increase in the second half of 2024 as we plan to advance our next generation GTB-3650 camelid nanobody product into the clinic, enroll patients, and perform tests for data collection. We also plan to complete the product development of GTB-5550 and anticipate submission of IND application for GTB-5550 in the first half of 2025. We do not, however, anticipate an increase in related R&D licensing and administrative costs.

Selling, General, and Administrative Expenses

Selling, general, and administrative expenses increased by approximately \$1.1 million and \$3.0 million, for the three and nine months ended September 30, 2024 and 2023, respectively, primarily due to an increase in legal and professional fees and an accrual for the probable settlement of a legal matter where the amount of the settlement can be reasonably estimated.

Other Income (Expense)

| | Three Months Ended September 30, | | | |
|---|----------------------------------|-------------------|---------------------|--------------|
| | 2024 | 2023 | \$ Change | % Change |
| Other Income (Expense): | | | | |
| Interest income | \$ 96,000 | \$ 216,000 | \$ (120,000) | (56)% |
| Change in fair value of warrant liability | 95,000 | 485,000 | (390,000) | (80)% |
| Unrealized gain (loss) on marketable securities | 2,000 | 5,000 | (3,000) | (60)% |
| Total Other Income (Expense) | \$ 193,000 | \$ 706,000 | \$ (513,000) | (73)% |

| | Nine Months Ended September 30, | | | |
|---|---------------------------------|---------------------|-----------------------|--------------|
| | 2024 | 2023 | \$ Change | % Change |
| Other Income (Expense): | | | | |
| Interest income | \$ 343,000 | \$ 600,000 | \$ (257,000) | (43)% |
| Interest expense | — | (213,000) | 213,000 | 100% |
| Change in fair value of warrant liability | 870,000 | 4,796,000 | (3,926,000) | (82)% |
| Gain on extinguishment of debt | — | 547,000 | (547,000) | (100)% |
| Unrealized gain (loss) on marketable securities | 1,000 | 43,000 | (42,000) | (98)% |
| Total Other Income (Expense) | \$ 1,214,000 | \$ 5,773,000 | \$ (4,559,000) | (79)% |

Interest Income

Interest income decreased by \$120,000 and \$257,000 for the three and nine months ended September 30, 2024 compared to the same prior year periods, respectively, primarily due to lower short term investment balances.

Interest Expense

Interest expense decreased by \$213,000 for the nine months ended September 30, 2024 compared to the same prior year period, respectively, due to the financing costs incurred associated with warrants accounted as warrant liability, there were no similar transactions during the current period.

Change in Fair Value of Warrant Liability

The change in fair value of warrant liability decreased by approximately \$390,000 and \$3.9 million for the three and nine months ended September 30, 2024 compared to the same prior year periods, respectively, resulting from a reduction in our warrant liability due to the decline in the Company's stock price at September 30, 2024 as compared to the prior comparable periods.

Gain on Extinguishment of Debt

Gain on extinguishment of debt decreased by \$547,000 for the six months ended September 30, 2024 compared to the same prior year period, respectively, and resulted from share settlements of a greater amount of vendor accounts payable than the fair value of the shares on the date of settlement, there were no similar transactions during the current period.

Net Loss

| | Three Months Ended September 30, | | | |
|-----------------|----------------------------------|-----------------------|-------------------|------------|
| | 2024 | 2023 | \$ Change | % Change |
| Net Loss | \$ (3,411,000) | \$ (2,416,000) | \$ 995,000 | 41% |

| | Nine Months Ended September 30, | | | |
|-----------------|---------------------------------|-----------------------|---------------------|-------------|
| | 2024 | 2023 | \$ Change | % Change |
| Net Loss | \$ (9,387,000) | \$ (4,635,000) | \$ 4,752,000 | 103% |

Net loss increased \$995,000 for the three months ended September 30, 2024, primarily due to an increase in legal and professional fees and an accrual for the probable settlement of a legal matter, and the decrease in the change in fair value of warrant liability, all as described above.

Net loss increased \$4,752,000 for the nine months ended September 30, 2024, primarily due to the decrease in the change in fair value of warrant liability, an increase in legal and professional fees and an accrual for the probable settlement of a legal matter, and the decrease in the gain on extinguishment of debt, all as described above.

Liquidity and Going Concern Analysis

The accompanying unaudited condensed consolidated financial statements have been prepared assuming that we will continue as a going concern. We do not have any product candidates approved for sale and have not generated any revenue from our product sales. We have sustained operating losses since inception, and we expect such losses to continue into the foreseeable future. Historically, we have financed our operations through public and private sales of common stock, issuance of preferred and common stock, issuance of convertible debt instruments, and strategic collaborations. For the nine months ended September 30, 2024, we recorded a net loss of approximately \$9.4 million and used cash in operations of approximately \$10.4 million. These factors raise substantial doubt about our ability to continue as a going concern within one year of the date that the financial statements are issued.

The unaudited condensed consolidated financial statements do not include any adjustments that might be necessary if we are unable to continue as a going concern. Accordingly, the unaudited condensed consolidated financial statements have been prepared on a basis that assumes we will continue as a going concern, and which contemplates the realization of assets and satisfaction of liabilities and commitments in the ordinary course of business.

We have evaluated the significance of the uncertainty regarding our financial condition in relation to our ability to meet our obligations, which has raised substantial doubt about our ability to continue as a going concern. While it is very difficult to estimate our future liquidity requirements we believe if we are unable to obtain additional financing, existing cash resources will not be sufficient to enable us to fund the anticipated level of operations through one year from the date the accompanying unaudited condensed consolidated financial statements are issued. There can be no assurances that we will be able to secure additional financing on acceptable terms. In the event that we do not secure additional financing, we will be forced to delay, reduce, or eliminate some or all of our discretionary spending, which could adversely affect our business prospects, ability to meet long-term liquidity needs and the ability to continue operations.

Cash Flows

| | Nine Months Ended September 30, | |
|--|--|---------------------|
| | 2024 | 2023 |
| Consolidated Statements of Cash Flow Data: | | |
| Net cash used in operating activities | \$ (10,436,000) | \$ (6,805,000) |
| Net cash provided by (used in) investing activities | 12,892,000 | (2,487,000) |
| Net cash provided by financing activities | 2,976,000 | 6,268,000 |
| Net increase (decrease) in cash and cash equivalents and restricted cash | 5,432,000 | (3,024,000) |
| Cash and cash equivalents and restricted cash, beginning of period | 1,079,000 | 5,672,000 |
| Cash and cash equivalents and restricted cash, end of period | <u>\$ 6,511,000</u> | <u>\$ 2,648,000</u> |

Operating Activities

Net cash used in operating activities was \$10.4 million for the nine months ended September 30, 2024, and was primarily due to a net loss of \$9.4 million, and a decrease in the fair value of warrant liability of \$0.9 million.

Net cash used in operating activities was \$6.8 million for the nine months ended September 30, 2023, and was primarily due to a net loss of \$4.6 million, a decrease in the fair value of warrant liability of \$4.8 million, and partially offset by stock compensation of \$1.3 million and an increase in accounts payable and accrued expenses of \$1.4 million.

Investing Activities

Net cash provided (used) in financing activities for the nine months ended September 30, 2024 and 2023, resulted primarily from proceeds from the sale, or (purchase), of short-term investments.

Financing Activities

Net cash provided by financing activities for the nine months ended September 30, 2024 and 2023, resulted from proceeds from the issuance of common stock and warrants.

Working Capital

The following table summarizes total current assets, liabilities, and working capital for the periods ended September 30, 2024 and December 31, 2023:

| | As of | | Increase/(Decrease) |
|---------------------|-----------------------|----------------------|---------------------|
| | September 30, 2024 | December 31, 2023 | |
| Current assets | \$ 6,759,000 | \$ 14,056,000 | \$ (7,297,000) |
| Current liabilities | \$ 4,662,000 | \$ 6,633,000 | \$ (1,971,000) |
| Working capital | \$ 2,097,000 | \$ 7,423,000 | \$ (5,326,000) |

Off-Balance Sheet Arrangements

We have no off-balance sheet arrangements as of September 30, 2024.

Item 3. Quantitative and Qualitative Disclosures About Market Risk

Our Company qualifies as a smaller reporting company, as defined in 17 C.F.R. §229.10(f)(1) and is not required to provide information for this Item.

Item 4. Controls and Procedures

Evaluation of Disclosure Controls and Procedures

Our Principal Executive Officer, Principal Financial Officer and Principal Accounting Officer evaluated the effectiveness of our “disclosure controls and procedures” (as such term is defined in Rules 13a-15(e) and 15d-15(e) of the United States Securities Exchange Act of 1934, as amended), as of September 30, 2024. Based on that evaluation, we have concluded that our disclosure controls and procedures were effective as of September 30, 2024.

Management’s Report on Internal Control Over Financial Reporting

Management is responsible for establishing and maintaining adequate internal control over financial reporting. Internal control over financial reporting is defined in Rule 13a-15(f) or 15d-15(f) promulgated under the Securities Exchange Act of 1934, as amended, as a process designed by, or under the supervision of, a company’s principal executive and principal accounting officers and effected by a company’s board of directors, management and other personnel, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of consolidated financial statements for external purposes in accordance with GAAP and includes those policies and procedures that:

- Pertain to the maintenance of records that in reasonable detail accurately and fairly reflect the transactions and dispositions of our assets
- Provide reasonable assurance that transactions are recorded as necessary to permit preparation of consolidated financial statements in accordance with GAAP, and that our receipts and expenditures are being made only in accordance with authorizations of our management and directors; and
- Provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use or disposition of our assets that could have a material effect on the consolidated financial statements.

Inherent Limitations on the Effectiveness of Controls

Management does not expect that our disclosure controls and procedures or our internal control over financial reporting will prevent or detect all errors and all fraud. A control system, no matter how well conceived and operated, can provide only reasonable, not absolute, assurance that the objectives of the control systems are met. Further, the design of a control system must reflect the fact that there are resource constraints, and the benefits of controls must be considered relative to their costs. Because of the inherent limitations in a cost-effective control system, no evaluation of internal control over financial reporting can provide absolute assurance that misstatements due to error or fraud will not occur or that all control issues and instances of fraud, if any, have been or will be 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. Controls can also 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 based in part on 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. Projections of any evaluation of controls effectiveness to future periods are subject to risks. Over time, controls may become inadequate because of changes in conditions or deterioration in the degree of compliance with policies or procedures.

Changes in Internal Control Over Financial Reporting

No changes in our internal controls over financial reporting were made during our most recent fiscal quarter that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

PART II. OTHER INFORMATION

Item 1. Legal Proceedings

Ohri Matter

On July 22, 2024, the Company filed an AAA Arbitration Demand against Manu Ohri, its former Chief Financial Officer. In the Demand, the Company asserts claims against Mr. Ohri for breach of his fiduciary duties and breach of contract and seeks a declaratory judgment providing that the Company may characterize Mr. Ohri's termination as "for cause" under his Employment Agreement, and that the Company may revoke the Separation Agreement entered into between the Company and Mr. Ohri prior to the Company learning of Mr. Ohri's breaches. In addition to the declaratory judgment, the Company seeks damages arising from Mr. Ohri's violations, and attorneys' fees and any forum and arbitration fees. On September 3, 2024, Mr. Ohri filed both a general denial of the Company's claims against him and counterclaims for breach of his Employment Agreement and Separation Agreement. At this early stage in the proceedings the Company is not able to determine the probability of the outcome of this matter or a range of reasonably expected losses, if any.

Berk Matter

On November 14, 2023, former interim Chief Executive Officer, Dr. Gregory Berk filed a lawsuit in the U.S. District Court for the District of Massachusetts alleging that the Company discriminated and retaliated against Dr. Berk for engaging in protected whistleblowing activity in violation of the Sarbanes Oxley Act ("SOX"). The Company vigorously defended this matter and believes it to be without merit; however, the parties have agreed to resolve the matter and the Company expects the lawsuit to be dismissed shortly. The Company believes it has recorded appropriate accruals for the matter.

TWF Global Matter

On May 24, 2023, TWF Global, LLC ("TWF") filed a Complaint in the California Superior Court for the County of Los Angeles naming the Company as defendant. The Complaint alleges that TWF is the holder of two Convertible Promissory Notes ("Notes") and that the Company did not deliver shares of common stock due on conversion in February 2021. TWF was seeking per diem liquidated damages based on the terms of alleged Notes. On July 14, 2023, the Company filed a motion to dismiss for improper forum because the terms of the Notes, as alleged, require disputes to be filed in New York state and federal courts. TWF voluntarily dismissed its Complaint before the California Superior Court of Los Angeles without prejudice. The Company subsequently filed a Summons and Complaint for Interpleader against TWF and Z-One LLC before the Supreme Court of the State of New York County of New York, asking the Supreme Court to determine if the Company's shares of common stock are properly registered to TWF or Z-One LLC, as both of these entities have made conflicting demands for registration of the shares of common stock. On February 5, 2024, the Company filed a motion for entry of default against TWF, seeking an order directing the Company to register the shares of common stock in the name of Z-One and that the Company be released from all associated liability and claims. The Court denied the motion without prejudice and will reconsider the motion without further briefing upon the filing of a supplemental party affidavit. On May 9, 2024, Z-One filed a motion for summary judgement seeking dismissal of the action, representing that Z-One and TWF have settled their dispute over the entitlement to the Company's shares of common stock and there is no remaining dispute before the Court. On May 21, 2024, the Company filed a supplemental affidavit in support of its motion for entry of default. The Court has set a hearing on Z-One's motion for November 14, 2024. The Company believes that any claims related to the Notes are without merit and will continue to defend vigorously against these claims.

Item 6. Exhibits

| <u>Exhibit</u> | <u>Description</u> | <u>Filed Herewith</u> | <u>Form</u> | <u>Number</u> | <u>SEC File No.</u> | <u>Filing Date</u> |
|----------------|---|---------------------------|-------------|---------------|---------------------|--------------------|
| 3.1 | Restated Certificate of Incorporation as filed in Delaware September 10, 1996 and as thereafter amended through March 1, 2002 | | 10-KSB | 3.A | 000-08092 | 4/1/2002 |
| 3.2 | Certificate of Amendment to the Restated Certificate of Incorporation of GT Biopharma, Inc., dated February 9, 2011 | | 10-K | 3.2 | 000-08092 | 3/31/2011 |
| 3.3 | Certificate of Amendment to the Restated Certificate of Incorporation of GT Biopharma, Inc., effective as of July 19, 2017 | | 8-K/A | 3.1 | 000-08092 | 3/15/2018 |
| 3.4 | Certificate of Amendment to the Restated Certificate of Incorporation of GT Biopharma, Inc., effective as of February 10, 2021 | | 8-K | 3.1 | 001-40023 | 2/11/2021 |
| 3.5 | Certificate of Amendment to Restated Certificate of Incorporation of the Registrant effective June 13, 2022 | | 10-K | 3.5 | 001-40023 | 3/30/2023 |
| 3.6 | Certificate of Amendment to Restated Certificate of Incorporation of the Registrant effective February 1, 2024 | | 8-K | 3.1 | 001-40023 | 2/1/2024 |
| 3.7 | Amended and Restated Bylaws of GT Biopharma, Inc. effective November 3, 2022 | | 8-K | 3.1 | 001-40023 | 11/9/2022 |
| 4.1 | Certificate of Designation of Preferences, Rights and Limitations of Series J-1 Preferred Stock of GT Biopharma, Inc., dated April 3, 2019 | | 8-K | 3.1 | 000-08092 | 4/4/2019 |
| 4.2 | Certificate of Designation of Preferences, Rights and Limitations of Series K Preferred Stock of GT Biopharma, Inc. dated April 3, 2019 | | 10-K | 4.2 | 001-40023 | 4/16/2021 |
| 4.3 | Form of Common Warrant | | 8-K | 4.1 | 001-40023 | 5/23/2024 |
| 31.1 | Certification of Principal Executive Officer pursuant to Rule 13a-14 and Rule 15d-14(a), promulgated under the Securities and Exchange Act of 1934, as amended. | X | | | | |
| 31.2 | Certification of Principal Executive Officer pursuant to Rule 13a-14 and Rule 15d-14(a), promulgated under the Securities and Exchange Act of 1934, as amended. | X | | | | |
| 32.1 | Certification of Principal Executive Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to section 906 of the Sarbanes-Oxley Act of 2002* | X | | | | |
| 32.2 | Certification of Principal Executive Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to section 906 of the Sarbanes-Oxley Act of 2002* | X | | | | |
| 101.INS | Inline XBRL Instance Document. | X | | | | |
| 101.SCH | Inline XBRL Taxonomy Extension Schema Document. | X | | | | |
| 101.CAL | Inline XBRL Taxonomy Extension Calculation Linkbase | X | | | | |
| 101.DEF | Inline XBRL Taxonomy Extension Definition Linkbase | X | | | | |
| 101.LAB | Inline XBRL Taxonomy Extension Label Linkbase Document. | X | | | | |
| 101.PRE | Inline XBRL Taxonomy Extension Presentation Linkbase | X | | | | |
| 104 | Cover Page Interactive Data File (embedded within the Inline XBRL document) | X | | | | |

* This certification shall not be deemed “filed” for purposes of Section 18 of the Exchange Act, or otherwise subject to the liability of that Section, nor shall it be deemed to be incorporated by reference into any filing under the Securities Act or the Exchange Act.

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.

GT BIOPHARMA, INC.

Dated: November 14, 2024

By: /s/ Michael Breen
Michael Breen
Interim Chief Executive Officer and
Executive Chairman of the Board
(Principal Executive Officer)

Dated: November 14, 2024

By: /s/ Alan Urban
Alan Urban
Chief Financial Officer & Secretary
(Principal Financial and Accounting Officer)

CERTIFICATION PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT

I, Michael Breen, certify that:

- a. I have reviewed this report on Form 10-Q of GT Biopharma, Inc.;
- b. 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;
- c. 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;
- d. I am 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:
 - i) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
 - ii) 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;
 - iii) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
 - iv) 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
- e. 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):
 - i) 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
 - ii) any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: November 14, 2024

By: /s/ Michael Breen

Name: Michael Breen

Title: Interim Chief Executive Officer and
Executive Chairman of the Board
(Principal Executive Officer)

CERTIFICATION PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT

I, Alan Urban, certify that:

- a. I have reviewed this report on Form 10-Q of GT Biopharma, Inc.;
- b. 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;
- c. 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;
- d. I am 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:
 - i) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
 - ii) 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;
 - iii) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
 - iv) 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
- e. 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):
 - i) 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
 - ii) any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: November 14, 2024

By: /s/ Alan Urban
Name: Alan Urban
Title: Chief Financial Officer & Secretary
(Principal Financial Officer)

CERTIFICATION TO SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

Pursuant to 18 U.S.C. § 1350, as created by Section 906 of the Sarbanes-Oxley Act of 2002, I, Michael Breen, Chief Executive Officer of GT Biopharma, Inc. (the "Company"), hereby certify that, to the best of my knowledge:

(i) the Quarterly Report on Form 10-Q of the Company for the fiscal quarter ended September 30, 2024 (the "Report") fully complies with the requirements of Section 13(a) or Section 15(d), as applicable, of the Securities Exchange Act of 1934, as amended; and

(ii) the information contained in the Report fairly presents, in all material respects, the financial condition and results of operation of the Company.

Date: November 14, 2024

By: /s/ Michael Breen

Name: Michael Breen

Title: Interim Chief Executive Officer and
Executive Chairman of the Board
(Principal Executive Officer)

CERTIFICATION TO SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

Pursuant to 18 U.S.C. § 1350, as created by Section 906 of the Sarbanes-Oxley Act of 2002, I, Alan Urbani, Chief Financial Officer and Principal Accounting Officer of GT Biopharma, Inc. (the "Company"), hereby certify that, to the best of my knowledge:

(i) the Quarterly Report on Form 10-Q of the Company for the fiscal quarter ended September 30, 2024 (the "Report") fully complies with the requirements of Section 13(a) or Section 15(d), as applicable, of the Securities Exchange Act of 1934, as amended; and

(ii) the information contained in the Report fairly presents, in all material respects, the financial condition and results of operation of the Company.

Date: November 14, 2024

By: /s/ Alan Urban

Name: Alan Urban

Title: Chief Financial Officer & Secretary
(Principal Financial Officer)
