

**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, 2023.

☐ 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)

8000 Marina Blvd, Suite 100
Brisbane, CA 94005
(Address of principal executive offices and zip code)
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 ☐
Non-accelerated filer ☒
Emerging growth company ☐

Accelerated filer ☐
Smaller reporting 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 1, 2023, the registrant had 41,418,999 shares of common stock outstanding.

GT BIOPHARMA, INC. AND SUBSIDIARIES
FORM 10-Q
For the Nine Months Ended September 30, 2023
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GT BIOPHARMA, INC. AND SUBSIDIARIES
CONDENSED CONSOLIDATED BALANCE SHEETS
(in thousands, except shares and par value)

	September 30, 2023 (Unaudited)	December 31, 2022
ASSETS		
Current assets		
Cash and cash equivalents	\$ 2,648	\$ 5,672
Short-term investments	13,366	10,836
Prepaid expenses and other current assets	38	54
Total Current Assets	<u>16,052</u>	<u>16,562</u>
Operating lease right-of-use asset	87	165
Deposits	9	9
TOTAL ASSETS	<u><u>\$ 16,148</u></u>	<u><u>\$ 16,736</u></u>
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities		
Accounts payable	\$ 3,970	\$ 3,140
Accrued expenses	1,028	1,669
Current operating lease liability	92	110
Total Current Liabilities	<u>5,090</u>	<u>4,919</u>
Non-current operating lease liability	-	64
Warrant liability	1,053	19
Total Liabilities	<u><u>6,143</u></u>	<u><u>5,002</u></u>
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, 2023 and December 31, 2022, respectively	1	1
Common stock, par value \$0.001, 250,000,000 shares authorized, 41,418,999 shares and 32,722,452 shares issued and outstanding as of September 30, 2023 and December 31, 2022, respectively	42	33
Additional paid in capital	689,065	686,168
Accumulated deficit	(679,103)	(674,468)
Total Stockholders' Equity	<u>10,005</u>	<u>11,734</u>
TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY	<u><u>\$ 16,148</u></u>	<u><u>\$ 16,736</u></u>

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

GT BIOPHARMA, INC. AND SUBSIDIARIES
CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS
(in thousands, except per share data)

	For The Three Months Ended September 30,		For the Nine Months Ended September 30,	
	2023	2022	2023	2022
	(Unaudited)	(Unaudited)	(Unaudited)	(Unaudited)
Revenues	\$ -	\$ -	\$ -	\$ -
Operating Expenses:				
Research and development (including \$0 and \$201 expense from stock compensation granted to officers, directors and employees during the three months ended September 30, 2023 and 2022, and \$13 and \$327 for the nine months ended September 30, 2023 and 2022, respectively)	1,364	2,743	5,109	5,969
Selling, general and administrative (including \$0.5 million and \$2.7 million expense from stock compensation granted to officers, directors and employees during the three months ended September 30, 2023 and 2022, respectively and \$1.8 million and \$3.5 million for the nine months ended September 30, 2023 and 2022, respectively)	1,758	4,280	5,299	9,510
Loss from Operations	(3,122)	(7,023)	(10,408)	(15,479)
Other (Income) Expense				
Interest income	(216)	(107)	(600)	(151)
Interest expense	-	-	213	-
Change in fair value of derivative liability	(485)	(58)	(4,796)	(81)
Gain on extinguishment of debt	-	-	(547)	-
Unrealized (gain) loss on short term investments	(5)	23	(43)	53
Total Other (Income) Expense	(706)	(142)	(5,773)	(179)
Net Loss	\$ (2,416)	\$ (6,881)	\$ (4,635)	\$ (15,300)
Net Loss Per Share - Basic and Diluted	\$ (0.06)	\$ (0.22)	\$ (0.12)	\$ (0.48)
Weighted average common shares outstanding - basic and diluted	41,016,075	31,380,634	40,095,945	31,723,792

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
(in thousands)

For The Three Months Ended September 30, 2023 (Unaudited)

	Preferred Shares		Common Shares		Common Shares Issuable		Additional Paid in Capital	Accumulated Deficit	Total
	Shares	Amount	Shares	Amount	Shares	Amount			
Balance, June 30, 2023	96	\$ 1	40,640	\$ 41	-	\$ -	\$ 688,408	\$ (676,687)	\$ 11,763
Fair value of vested stock options	-	-	-	-	-	-	433	-	433
Issuance of common stock to an officer and a board member for services	-	-	400	1	-	-	114	-	115
Issuance of common stock in settlement of accounts payable and accrued expenses	-	-	379	-	-	-	110	-	110
Net loss	-	-	-	-	-	-	-	(2,416)	(2,416)
Balance, September 30, 2023	96	\$ 1	41,419	\$ 42	-	\$ -	\$ 689,065	\$ (679,103)	\$ 10,005

For The Nine Months Ended September 30, 2023 (Unaudited)

	Preferred Shares		Common Shares		Common Shares Issuable		Additional Paid in Capital	Accumulated Deficit	Total
	Shares	Amount	Shares	Amount	Shares	Amount			
Balance, December 31, 2022	96	\$ 1	32,723	\$ 33	-	\$ -	\$ 686,168	\$ (674,468)	\$ 11,734
Private placement of common stock	-	-	3,600	4	-	-	6,264	-	6,268
Initial recognition of fair value of warrant liability	-	-	-	-	-	-	(5,831)	-	(5,831)
Fair value of vested stock options	-	-	-	-	-	-	1,337	-	1,337
Issuance of common stock to officer and board member for services	-	-	473	-	-	-	430	-	430
Issuance of common stock for exercise of Prefunded Warrants	-	-	2,900	3	-	-	(3)	-	-
Issuance of common stock in settlement of accounts payable and accrued expenses	-	-	1,723	2	-	-	700	-	702
Net loss	-	-	-	-	-	-	-	(4,635)	(4,635)
Balance, September 30, 2023	96	\$ 1	41,419	\$ 42	-	\$ -	\$ 689,065	\$ (679,103)	\$ 10,005

For The Three Months Ended September 30, 2022 (Unaudited)

	Preferred Shares		Common Shares		Common Shares Issuable		Additional Paid in Capital	Accumulated Deficit	Total
	Shares	Amount	Shares	Amount	Shares	Amount			
Balance, June 30, 2022	96	\$ 1	30,694	\$ 31	-	\$ -	\$ 677,411	\$ (662,003)	\$ 15,440
Equity compensation to officers, employees, and board of directors	-	-	78	-	378	938	2,006	-	2,944
Issuance of common shares for services	-	-	135	-	-	-	1,200	-	1,200
Issuance of common shares in settlement of vendors payable	-	-	1,222	1	-	-	3,250	-	3,251
Net loss	-	-	-	-	-	-	-	(6,881)	(6,881)
Balance, September 30, 2022	<u>96</u>	<u>\$ 1</u>	<u>32,129</u>	<u>\$ 32</u>	<u>378</u>	<u>\$ 938</u>	<u>\$ 683,867</u>	<u>\$ (668,884)</u>	<u>\$ 15,954</u>

For The Nine Months Ended September 30, 2022 (Unaudited)

	Preferred Shares		Common Shares		Common Shares Issuable		Additional Paid in Capital	Accumulated Deficit	Total
	Shares	Amount	Shares	Amount	Shares	Amount			
Balance, December 31, 2021	96	\$ 1	32,062	\$ 32	327	\$ 1,113	\$ 674,348	\$ (653,584)	\$ 21,910
Cancellation of common stock upon settlement with former officer	-	-	(1,845)	(1)	-	-	(222)	-	(223)
Cancellation of common stock	-	-	(291)	-	-	-	-	-	-
Common shares issued upon conversion of notes payable	-	-	327		(327)	(1,113)	1,113	-	-
Equity compensation to officers, employees, and board of directors	-	-	242	-	378	938	2,916	-	3,854
Issuance of common shares for services	-	-	412	-	-	-	2,462	-	2,462
Issuance of common shares in settlement of vendors payable	-	-	1,222	1	-	-	3,250	-	3,251
Net loss	-	-	-	-	-	-	-	(15,300)	(15,300)
Balance, September 30, 2022	<u>96</u>	<u>\$ 1</u>	<u>32,129</u>	<u>\$ 32</u>	<u>378</u>	<u>\$ 938</u>	<u>\$ 683,867</u>	<u>\$ (668,884)</u>	<u>\$ 15,954</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
(in thousands)

	For The Nine Months Ended September 30,	
	2023	2022
	(Unaudited)	(Unaudited)
CASH FLOWS FROM OPERATING ACTIVITIES		
Net loss	\$ (4,635)	\$ (15,300)
Adjustments to reconcile net loss to net cash used in operating activities:		
Stock based compensation – common shares for services	430	5,713
Stock based compensation – vested stock options	1,337	3,854
Change in fair value of warrant liability	(4,796)	(81)
Gain on extinguishment of debt	(547)	-
Unrealized (gain) loss on marketable securities	(43)	53
Changes in operating assets and liabilities:		
Decrease in prepaid expenses	16	102
Increase in deposits	-	(9)
Decrease in operating lease right of use assets	78	70
Increase (decrease) in accounts payable and accrued expenses	1,437	(5,259)
(Decrease) in operating lease liability	(82)	(62)
Net Cash Used in Operating Activities	(6,805)	(10,919)
CASH FLOWS FROM INVESTING ACTIVITIES		
Sales (purchases) of investments	(2,487)	4,639
Net Cash Provided by (Used in) Investing Activities	(2,487)	4,639
CASH FLOWS FROM FINANCING ACTIVITIES		
Proceeds from issuance of common stock and prefunded warrants	6,268	-
Cancellation of common stock upon settlement with former officer	-	(223)
Net Cash (Used in) Provided by Financing Activities	6,268	(223)
Net Decrease in Cash	(3,024)	(6,503)
Cash at Beginning of Period	5,672	8,968
Cash at End of Period	\$ 2,648	\$ 2,465
<u>SUPPLEMENTAL DISCLOSURES OF CASH FLOW INFORMATION:</u>		
Cash paid during the year for:		
Interest	\$ -	\$ -
Income taxes paid	\$ -	\$ -
<u>SUPPLEMENTAL DISCLOSURES OF NON-CASH INVESTING AND FINANCING ACTIVITIES</u>		
Right-of-use assets exchanged for lease liabilities	\$ -	\$ 260
Initial recognition of fair value of warrant liability	\$ 5,831	\$ -
Fair value of common stock issued to settle accounts payable and accrued expenses	\$ 700	\$ -
Common stock issued upon conversion of notes payable and accrued interest	\$ -	\$ 1,113

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

GT BIOPHARMA, INC. AND SUBSIDIARIES
NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS
September 30, 2023 and 2022
(Unaudited, in thousands, except shares data)

Note 1 – Organization and Operations

In 1965, the corporate predecessor of GT Biopharma, Inc. (Company), Diagnostic Data, Inc. was incorporated in the State of California. Diagnostic Data changed its incorporation to the State of Delaware in 1972 and changed its name to DDI Pharmaceuticals, Inc. in 1985. In 1994, DDI Pharmaceuticals merged with International BioClinical, Inc. and Bioxytech S.A. and changed its name to OXIS International, Inc. In July 2017, the Company changed its name to GT Biopharma, Inc.

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).

Note 2 – Summary of Significant Accounting Policies

Basis of Presentation and Principles of Consolidation

The consolidated condensed 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 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, 2022, filed with the SEC on March 30, 2023 (the "2022 Annual Report"). The consolidated balance sheets as of December 31, 2022 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 its 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.

Liquidity

The accompanying consolidated financial statements have been prepared under the assumption that the Company will continue as a going concern. Such assumptions contemplate the realization of assets and satisfaction of liabilities in the normal course of business. For the nine months ended September 30, 2023, the Company recorded a net loss of \$4.6 million and used cash in operations of \$6.8 million. As of September 30, 2023, the Company had a cash and short-term investments balance of \$16.0 million, working capital of \$11.0 million, and stockholders' equity of \$10.0 million. Management anticipates that the \$16.0 million of cash and cash equivalents, and short-term investments are adequate to satisfy the liquidity needs of the Company for at least one year from the date the Company's condensed consolidated financial statements for the nine-month period ended September 30, 2023 were issued.

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. 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 generate sufficient cash flows from investing and financing activities, 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 or ability to continue its operations.

COVID-19

The global COVID-19 pandemic continues to present uncertainty and unforeseeable risks to our operations and business plans. The Company has closely monitored recent developments, including the lifting of COVID-19 safety measures, the spread of new strains or variants of the coronavirus (such as the Delta and Omicron variants), and supply chain, raw materials and labor shortages. Thus, the full impact of the COVID-19 pandemic on the business and operations remains uncertain and will vary depending on the pandemic's future impact on the third parties with whom the Company does business, as well as any legal or regulatory consequences resulting therefrom. The Company has been following the recommendations of health authorities to minimize exposure risk for its team members and may take further actions that alter our operations, including any required by federal, state or local authorities, or that it determines are in the best interests of its employees and other third parties with whom GT Biopharma does business.

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 accruals for potential liabilities, assumptions used in deriving the fair value of warrant liabilities, valuation of equity instruments issued for debt and services and realization of deferred tax assets. Actual results could differ from those estimates.

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 condensed consolidated financial statements. Total cash equivalents, which consist of money market funds, totaled approximately \$2.5 million and \$5.5 million at September 30, 2023 and December 31, 2022, respectively.

The Company also invested its excess cash in commercial paper and corporate notes and bonds. 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 condensed consolidated statements of operations. Total short-term investments totaled approximately \$13.4 million and \$10.8 million at September 30, 2023 and December 31, 2022, respectively.

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 amount of the Company's warrant liability of \$1.1 million and \$0.02 million at September 30, 2023 and December 31, 2022, respectively, was based on Level 3 measurements.

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

Derivatives and Liability-Classified Instruments

The Company accounts for common stock warrants as either equity-classified or liability-classified instruments based on an assessment of the specific terms of the warrants and the guidance provided by the FASB in ASC 480, *Distinguishing Liabilities from Equity (ASC 480)* and ASC 815, *Derivatives and Hedging (ASC 815)*. The assessment considers whether the warrants are freestanding financial instruments pursuant to ASC 480, meet the definition of a liability pursuant to ASC 480, and meet all of the requirements for equity classification under ASC 815, including whether the warrants are indexed to the Company's own stock and whether the holders of the warrants could potentially require net cash settlement in a circumstance outside of the Company's control, among other conditions for equity classification. This assessment, which requires the use of professional judgment, is conducted at the time of warrant issuance and as of each subsequent quarterly period end date while the warrants are outstanding. The fair value of the warrant liability is determined using a Binomial valuation method at inception and on subsequent valuation dates.

Stock-Based Compensation

The Company accounts for share-based awards to employees, nonemployees, and consultants in accordance with the provisions of ASC 718, *Compensation-Stock Compensation*. Stock-based compensation cost is measured at fair value on the grant date and that fair value is recognized as expense over the requisite service or vesting period.

The Company values its equity awards using the Black-Scholes option pricing model, and accounts for forfeitures when they occur. Use of the Black-Scholes option pricing model requires the input of subjective assumptions including expected volatility, expected term, and a risk-free interest rate. The Company estimates volatility using its own historical stock price volatility. The expected term of the instrument is estimated by using the simplified method to estimate expected term. The risk-free interest rate is estimated using comparable published federal funds rates.

Research and Development Costs

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 costs. Purchased materials that do not have an alternative future use are also expensed.

Leases

The Company accounts for its leases 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 (see Note 8 – Operating Leases for the Company's lease disclosures).

Net Loss Per Share

Basic loss per share is computed using the weighted-average number of common shares outstanding during the period. Common stock issuable is included in our calculation as of the date of the underlying agreement. Diluted 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 for the exercise of stock options and warrants, have been excluded from the diluted loss per share calculation because their effect is anti-dilutive.

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

	September 30, 2023 (Unaudited)	September 30, 2022 (Unaudited)
Options to purchase common stock	3,737,952	1,835,452
Warrants to purchase common stock	9,148,880	2,337,274
Unvested restricted common stock	-	295,588
Total anti-dilutive securities	12,886,832	4,468,314

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. From time to time, however, the Company may be exposed to risk for the amounts of funds held in bank accounts in excess of the FDIC limit. To minimize the risk, the Company's policy is to maintain cash balances with high quality financial institutions.

The Company has a significant concentration of expenses incurred and accounts payable from a single vendor (see Note 4 – Accounts Payable for further information).

Segments

The Company determined its reporting units in accordance with ASC 280, "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.

Recent Accounting Pronouncements

In June 2016, the FASB issued Accounting Standards Update ("ASU") No. 2016-13, *Credit Losses – Measurement of Credit Losses on Financial Instruments* ("ASC 326"). ASU 2016-13 requires entities to use a forward-looking approach based on current expected credit losses ("CECL") to estimate credit losses on certain types of financial instruments, including trade receivables. This may result in the earlier recognition of allowances for losses. ASU 2016-13 was effective for the Company beginning January 1, 2023, and early adoption is permitted. The Company adopted this standard effective January 1, 2023 and there was no material impact of adopting this standard on the Company's financial statements and related disclosures.

In May 2021, the FASB issued ASU 2021-04, *Earnings Per Share (Topic 260), Debt-Modifications and Extinguishments (Subtopic 470-50), Compensation-Stock Compensation (Topic 718), and Derivatives and Hedging-Contracts in Entity's Own Equity (Subtopic 815-40): Issuer's Accounting for Certain Modifications or Exchanges of Freestanding Equity-Classified Written Call Options*. ASU 2021-04 provides clarification and reduces diversity in an issuer's accounting for modifications or exchanges of freestanding equity-classified written call options (such as warrants) that remain equity classified after modification or exchange. An issuer measures the effect of a modification or exchange as the difference between the fair value of the modified or exchanged warrant and the fair value of that warrant immediately before modification or exchange. ASU 2021-04 introduces a recognition model that comprises four categories of transactions and the corresponding accounting treatment for each category (equity issuance, debt origination, debt modification, and modifications unrelated to equity issuance and debt origination or modification). ASU 2021-04 was effective for fiscal years beginning after December 15, 2021, including interim periods within those fiscal years, applied prospectively to modifications or exchanges occurring on or after the effective date. Effective January 1, 2022, we adopted ASU 2021-04 using a prospective approach. It did not have a material impact on the Company's financial statements or disclosures.

Other recent accounting pronouncements issued by the FASB, including its Emerging Issues Task Force, the American Institute of Certified Public Accountants, and the SEC did not or are not believed by management to have a material impact on the Company's present or future consolidated financial statements.

Note 3 – Fair Value of Financial Instruments

The estimated fair values of financial instruments outstanding were as follow:

September 30, 2023 (Unaudited)				
	Cost	Unrealized Gains	Unrealized Losses	Fair Value
Short-term investments	\$ 13,323	\$ 43	\$ —	\$ 13,366
Total	\$ 13,323	\$ 43	\$ —	\$ 13,366

December 31, 2022				
	Cost	Unrealized Gains	Unrealized Losses	Fair Value
Short-term investments	\$ 10,866	\$ —	\$ (30)	\$ 10,836
Total	\$ 10,866	\$ —	\$ (30)	\$ 10,836

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

September 30, 2023 (Unaudited)				
	Fair Value	Level 1	Level 2	Level 3
Money market funds	\$ 2,474	\$ 2,474	\$ —	\$ —
Corporate notes and commercial paper	13,366	13,366	—	—
Total financial assets	<u>\$ 15,840</u>	<u>\$ 15,840</u>	<u>\$ —</u>	<u>\$ —</u>

December 31, 2022				
	Fair Value	Level 1	Level 2	Level 3
Money market funds	\$ 5,505	\$ 5,505	\$ —	\$ —
Corporate notes and commercial paper	10,836	10,836	—	—
Total financial assets	<u>\$ 16,341</u>	<u>\$ 16,341</u>	<u>\$ —</u>	<u>\$ —</u>

As of September 30, 2023, the fair value of the warrant liability amounted to \$1,053. The details of warrant liability transactions for the three and six months ended September 30, 2023 and 2022, are as follows:

	Three Months Ending		Nine Months Ending	
	September 30, 2023 (Unaudited)	September 30, 2022 (Unaudited)	September 30, 2023 (Unaudited)	September 30, 2022 (Unaudited)
Beginning balance	\$ 1,538	\$ 115	\$ 19	\$ 138
Fair value upon issuance of warrants	—	—	5,830	—
Change in fair value	(485)	(58)	(4,796)	(81)
Ending balance	<u>\$ 1,053</u>	<u>\$ 57</u>	<u>\$ 1,053</u>	<u>\$ 57</u>

Note 4 – Accounts Payable

Accounts payable consisted of the following:

	September 30, 2023 (Unaudited)	December 31, 2022
Accounts payable to a third-party manufacturer	\$ 3,144	\$ 2,283
Other accounts payable	826	857
Total accounts payable	<u>\$ 3,970</u>	<u>\$ 3,140</u>

The Company relies on a third-party contract manufacturing operation to produce and/or test our compounds used in our potential product candidates.

In October 2020, the Company entered into a Master Services Agreement with a third-party product manufacturer to perform biologic development and manufacturing services on behalf of the Company. Associated with this, the Company has subsequently executed a number of Statements of Work for the research and development of products for use in clinical trials.

On August 24, 2022, existing agreements with the third-party product manufacturer were amended. As part of the amendment, the third-party manufacturer agreed that services to be rendered in future periods, will be paid or settled at the Company's discretion, in a combination of cash and issuance of the Company's common stock. The amendment also eliminated future financial commitments of the Company.

During the nine months ended September 30, 2023 the Company incurred \$3.7 million in research and development expenses to account for services rendered by the third-party product manufacturer. In addition, the Company paid cash of \$1.7 million and issued 1.3 million shares of its common stock with a fair value of \$0.59 million in settlement of accounts payable of \$1.1 million, which resulted in a gain on settlement of \$0.55 million. The shares were valued at the respective date of issuance.

The outstanding accounts payable balance due to the third-party product manufacturer totaled \$3.1 million and \$2.3 million as of September 30, 2023 and December 31, 2022, respectively.

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 6,500,000 shares of the Company's common stock (the "Common Warrants"), and placement agent warrants to purchase up to 390,000 shares of the Company's common stock (the "Placement Agents Warrants" see Note 6 – Stockholders' Equity).

The Purchase Warrant provides for a value calculation for the Purchase Warrant 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 of the Purchase Warrant 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 Purchase Warrant as a liability in its consolidated balance sheet. The classification of the Purchase Warrant, including whether the Purchase Warrant should be recorded as liability or as equity, is evaluated at the end of each reporting period with changes in the fair value reported in other income (expense) in the consolidated statements of operations and comprehensive loss. The Purchase Warrant was initially recorded at a fair value at \$5.8 million at the grant date and is re-valued at each reporting date. Upon the closing of placement, the fair value of the Purchase Warrant liability was recorded as a cost of capital.

As of September 30, 2023, the fair value of the warrant liability was \$1.3 million.

All changes in the fair value of the warrant liabilities are recognized as a change in fair value of warrant liability in the Company's condensed consolidated statements of operations until they are either exercised or expire.

The warrant liabilities for the Common Warrants and the Placement Agents Warrants were valued using a Binomial pricing model with the following weighted average assumptions:

	Common Warrants and Placement Agents Warrants	
	September 30, 2023 (Unaudited)	At Inception (Unaudited)
Stock price	\$ 0.24	\$ 1.20
Risk-free interest rate	4.6%	3.60%
Expected volatility	119.7%	121.5%
Expected life (in years)	4.5	5.0
Expected dividend yield	-	-
Fair value of warrants (in thousands)	\$ 1,053	\$ 5,831

2020 Warrants

The Company issued certain warrants during the year ended December 31, 2020 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 these warrants is classified as a liability in the Condensed Consolidated Balance Sheets and will be re-measured at the end of every reporting period with the change in value reported in the Condensed Consolidated Statements of Operations.

The warrant liabilities for the 2020 Warrants were valued using a Binomial pricing model with the following assumptions:

	September 30, 2023 (Unaudited)	December 31, 2022
Stock price	\$ 0.24	\$ 0.89
Risk-free interest rate	4.95%	4.22%
Expected volatility	89%	109%
Expected life (in years)	1.8	2.6
Expected dividend yield	-	-
Fair value of warrants	\$ 2	\$ 19

During the three months and nine months ended September 30, 2023, the Company recognized a gain of \$0.5 million and \$4.8 million to account for the change in fair value of the warrant liability between the reporting periods in accordance with ASC 842. During the three months and nine months ended September 30, 2022, the Company recognized a gain of \$0.06 million and \$0.08 million to account for the change in the fair value of the warrant liability.

The risk-free interest rate was based on rates established by the Federal Reserve Bank. The Company uses the historical volatility of its common stock to estimate the future volatility for its common stock. The expected life of the warrant securities was determined by the remaining contractual life of the warrant instrument. The expected dividend yield was based on the fact that the Company has not paid dividends to its common stockholders in the past and does not expect to pay dividends to its common stockholders in the future.

Note 6 – Stockholders’ Equity

The Company’s authorized capital as of September 30, 2023 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

Private Placement of Common Stock

On January 4, 2023, GT Biopharma received gross proceeds of \$6.5 million, before deducting placement agent fees and other offering expenses of \$232 in relation to a purchase agreement (the “Purchase Agreement”) signed on December 30, 2022, between the Company and an institutional investor (the “Purchaser”) for the issuance and sale, in a registered direct offering (the “Offering”), of 3,600,000 shares of the Company’s common stock, par value \$0.001 per share (the “Shares”), pre-funded warrants to purchase up to 2,900,000 shares of the Company’s common stock (the “Pre-Funded Warrants”), warrants to purchase up to an aggregate of 6,500,000 shares of the Company’s common stock (the “Common Warrants”) and placement agent warrants to purchase up to 390,000 of the Company’s common stock (the “Placement Agents Warrants”). The Common Warrants have an exercise price equal to \$1.00, will be exercisable commencing six months following issuance, and will have a term of exercise equal to five years following the initial exercise date. The Pre-Funded Warrants have an exercise price of \$0.0001 per Share, are immediately exercisable and can be exercised at any time after their original issuance until such Pre-Funded Warrants are exercised in full. The Placement Agents Warrants have an exercise price equal to \$1.25, will be exercisable commencing six months following issuance, and will have a term of exercise equal to five years following the initial exercise date. The Shares and Common Warrants were sold at an offering price of \$1.00 per Share and accompanying Common Warrant and the Pre-Funded Warrants and Common Warrants were sold at an offering price of \$0.9999 per Pre-Funded Warrant and accompanying Common Warrant.

The Common Warrants and the 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 Common Warrants and the Placement Agent Warrants are not considered indexed to the Company’s own stock and not eligible for an exception from derivative accounting. Accordingly, the Common Warrants and the 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).

In May 2023, the 2,900,000 Pre-Funded Warrants were exercised. The Company received cash consideration of \$0.290 and issued 2,900,000 shares of common stock in exchange for the exercise price of \$0.0001 per share.

Common Stock Issuable

On February 16, 2021, because of the mandatory conversion of the notes payable and accrued interest in the aggregate amount of \$38.8 million, the Company issued a total of 11,413,322 shares of common stock to the respective noteholders, of which 11,086,024 were already issued as of December 31, 2021. The remaining 327,298 common shares valued at \$1.1 million, were issued during the three months ended March 31, 2022.

Cancellation of Common Stock

The Company cancelled 290,999 previously issued shares of common stock during the three months ended March 31, 2022.

Common Stock Issued for Services

During the three and nine months ended September 30, 2023, the Company issued 400 and 473 shares of common stock with a fair value of \$115 and \$430, respectively to members of the Board of Directors, employees and consultants. The shares were valued at the respective date of the agreements.

During the three and nine months ended September 30, 2022, the Company issued 135 and 412 shares of common stock with a fair value of \$1,200 and \$2,462, respectively to members of the Board of Directors, employees and consultants. The shares were valued at the respective date of the agreements.

Common Stock Issued for Accounts Payable

During the nine months ended September 30, 2023, the Company issued a total of 1,723,094 shares of common stock with a fair value of \$702 to settle accounts payable and accrued expenses of \$1.2 million. As a result, the Company recorded a gain of \$547 to account for the difference between the fair value of the common stock issued and the account payable settled. The common stock issued were valued at the respective date of their issuance.

Preferred Stock

Series C Preferred Stock

At September 30, 2023 and December 31, 2022, 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 convertible to common stock, 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 Company’s board of directors (the “Board”). No dividends to holders of the Series C Preferred Stock were declared or unpaid as of and for the period ended September 30, 2023.

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 an as-converted-to-common stock basis, in any distribution to holders of the Company’s common stock.

As of September 30, 2023 and December 31, 2022, there were no shares of Series K Preferred stock issued and outstanding.

Warrants and Options

Common Stock Warrants

Common stock warrant transactions for the nine months ended September 30, 2023 were as follows:

	Number of Warrants	Weighted Average Exercise Price
Warrant outstanding at December 31, 2022:	2,337,274	\$ 5.30
Granted	9,790,000	0.71
Forfeited/canceled	(78,394)	3.40
Exercised	(2,900,000)	0.0001
Warrants outstanding at September 30, 2023	9,148,880	\$ 2.11
Warrants exercisable at September 30, 2023	2,258,880	\$ 5.45

The warrants had an exercise price greater than the market price, which resulted in no intrinsic value.

Warrants outstanding as of September 30, 2023 are exercisable as follows:

Range of Exercise Price	Warrants Outstanding			Warrants Exercisable	
	Number Outstanding	Weighted Average Remaining Contractual Life (Years)	Weighted Average Exercise Price	Number Exercisable	Weighted Average Exercise Price
\$1.00 – 1.25	6,890,000	4.8	\$ 1.01	-	\$ -
3.40 – 5.50	2,258,880	2.4	5.45	2,258,880	5.45
	<u>9,148,880</u>			<u>2,258,880</u>	

Common Stock Options

Common stock option transactions for the nine months ended September 30, 2023 were as follows:

	Number of Options	Weighted Average Exercise Price
Options outstanding at December 31, 2022	1,630,452	\$ 2.57
Granted	2,500,000	0.75
Forfeited/canceled	(392,500)	2.81
Exercised	-	-
Options outstanding at September 30, 2023	<u>3,737,952</u>	<u>\$ 1.32</u>
Options vested and exercisable at September 30, 2023	<u>2,833,651</u>	<u>\$ 1.52</u>

The Company recognized the corresponding stock compensation expense for options granted to certain consultants, employees, officers and directors based upon their vesting term.

On January 27, 2023, the Company granted stock options to employees and members of its board of directors to purchase an aggregate of 2.0 million shares of common stock at an exercise price of \$0.85 per share. The stock options expire in 10 years, vest over twelve months and had a fair value of \$1.4 million at the date of grant determined using the Black-Scholes Option Pricing model with the following weighted average assumptions.

On May 15, 2023, the Company granted stock options to a member of its board of directors to purchase 500,000 shares of common stock at an exercise price of \$0.35 per share. The stock options expire in 10 years, vest over twelve months and had a fair value of \$150 on at the date of grant determined using the Black-Scholes Option Pricing model.

The Company used the following weighted average assumptions in the Black-Scholes Option Pricing model to compute the fair value of the stock options granted during the period ended September 30, 2023.

Stock price	\$	\$0.35 - \$0.85
Risk-free interest rate		3.62% - 3.99%
Expected volatility		120.81% - 123.61%
Expected life (in years)		5.3
Expected dividend yield		-

For the three months and nine months ended September 30, 2023, the Company recognized stock compensation expense relating to the vesting of options granted in 2023 and prior years of \$433 and \$1,337, respectively.

Options outstanding as of September 30, 2023 are exercisable as follows:

Options Outstanding				Options Exercisable				
Range of Exercise Price		Weighted Average Remaining Contractual Life		Weighted Average Exercise Price		Weighted Average Exercise Price		
		Number Outstanding	(Years)					
\$	2.48	1,237,952	8.8	\$	2.48	1,166,984	\$	2.48
	0.85	2,000,000	9.4		0.85	1,500,000		0.85
	0.35	500,000	9.7		0.35	166,667		0.35
		3,737,952				2,833,651		

At September 30, 2023, fair value of unvested options totaled \$904, which will be recognized as stock compensation expense in future periods based upon the remaining vesting term of the applicable grants.

There was no intrinsic value of the outstanding options as of September 30, 2023 as the exercise price of these options was greater than the market price.

Note 7 – 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 that have arisen under, and are being handled in, the normal course of business.

On May 11, 2023, our former interim Chief Executive Officer, Dr. Greg Berk, filed a complaint with the Occupational Safety and Health Administration alleging retaliation against him during his tenure at the Company for raising concerns related to the public disclosure of certain product timelines. The Company is vigorously defending this matter and believe it to be without merit. 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.

On May 13, 2022, the Company made a claim against Michael Handelman, its former Chief Financial Officer, asserting that he misappropriated Company funds and shares of common stock, and failed to file the required SEC reports on Form 3 and Form 4 regarding each acquisition and disposition of the Company's common stock. The Company seeks monetary damages estimated at \$370; the return of shares of our common stock received without authorization and the disgorgement of any profits earned from the sale of those shares; a full accounting for all sums charged on the Company's debit card, with payment to the Company for any charges that cannot be demonstrated to have a corporate purpose; an order directing Mr. Handelman to make all filings required by Section 16(a) of the 1934 Act; an award of all sums and shares improperly issued to members of Mr. Handelman's family; and an award of the Company's attorneys' fees and any forum and arbitration fees. As a component of Mr. Handelman's contract with the Company, disputes shall be fully addressed and finally resolved by binding arbitration conducted by the American Arbitration Association (AAA) in New York City, New York, in accordance with its National Employment Dispute Resolution rules. In connection with any such arbitration, the Company shall bear all costs not otherwise borne by a plaintiff in a court proceeding. The Company agrees that any decisions of the arbitration panel will be binding and enforceable in any state in which the Company conducts the operation of its business. In accordance with California Labor Laws, the Company has designated Los Angeles, California as the venue for this arbitration. The Company's claims have been heard by an arbitrator in Los Angeles and the decision of the arbitrator is currently pending. Mr. Handelman has not asserted any counterclaims against the Company.

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 has recently dismissed without prejudice its Complaint before the California Superior Court of Los Angeles. The Company also 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. The Company believes that TWF's claims are without merit and will continue to defend vigorously against these claims.

Significant Agreements

Research and Development Agreements

In June 2017, we entered into a co-development partnership agreement with Altor BioScience Corporation in which we will collaborate exclusively in the clinical development of a novel 161533 (GTB-3550) TriKE[®] fusion protein for cancer therapies using our TriKE[®] technology. The GTB-3550 Phase 1 clinical trial for treatment of patients with CD33-expressing, high risk myelodysplastic syndromes and refractory/relapsed acute myeloid leukemia opened for patient enrollment September 2019 and completed enrollment in September 2021. The results of our first generation GTB-3550 Phase 1 clinical trial support our plans to advance the next generation camelid nanobody into the clinic, and as such, no further clinical development will ensue with GTB-3550.

The Company is a party to a scientific research agreement with the Regents of the University of Minnesota ("UofMN"), effective June 16, 2021. This scientific research agreement aims to 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 here 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 us under current UMN/GTB licensing terms. This agreement expired on June 30, 2023. The Company and UofMN are negotiating the terms of the scientific research agreement and expect to finalize it by December 15, 2023. The UofMN shall use reasonable efforts to complete the project for a fixed sum of \$2.1 million.

For the three months and nine months ended September 30, 2023 and 2022, the Company recorded an expense of \$0.2 million and \$0.6 million pursuant to the scientific research agreement for each respective periods. The Company has recorded expense in the aggregate of \$2.1 million as of September 30, 2023 pursuant to this agreement.

Patent and License Agreements

2016 Exclusive Patent License Agreement

The Company is party to an exclusive worldwide license agreement with the Regents of the University of Minnesota, ("UofMN"), to further develop and commercialize cancer therapies using TriKE[®] technology developed by researchers at the UofMN to target NK cells to cancer. Under the terms of the 2016 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. Under the agreement, the UofMN received an upfront payment of \$200, and an annual License Maintenance fee of \$100 beginning in 2021. The agreement also includes 4% royalty fees, not to exceed 6% under subsequent license agreements or amendments to this agreement or minimum annual royalty payments ranging from \$250 to \$5.0 million. The agreement also includes certain performance milestone payments totaling \$3.1 million, and one-time sales milestone payments of \$1.0 million upon reaching \$250 million in gross sales, and \$5.0 million upon reaching \$500 million dollars in cumulative gross sales of Licensed Products.

The Company did not incur any research and development expense relating to the 2016 Exclusive Patent License Agreement for the three months and nine months ended September 30, 2023.

2021 Patent License Agreement

On March 26, 2021, the Company signed an agreement specific to the B7H3 targeted TriKE[®]. Under the agreement, the UofMN received an upfront license fee of \$20,000 and will receive an annual License Maintenance fee of \$5 beginning in 2022, 2.5% to 5% royalty fees, or minimum annual royalty payments of \$250 beginning in the year after the first commercial sales of Licensed Product, and \$2.0 million beginning in the fifth year after the first commercial sale of such Licensed Product. The agreement also includes certain performance milestone payments totaling \$3.1 million, and one-time sales milestone payments of \$1.0 million upon reaching \$250 million in gross sales, and \$5.0 million upon reaching \$500 million dollars 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 agreement no further payment is due for the corresponding milestone above.

The Company did not incur any research and development expense relating to the 2021 Patent License Agreement for the three months and nine months ended September 30, 2023.

Note 8 – Operating Leases

On November 19, 2021, the Company entered into a sublease with a third party for 4,500 square feet of office space located in Brisbane, California, with a commencement date of January 1, 2022 and maturing on June 30, 2024. Leases with an initial term of 12 months or less are not recorded on the balance sheet. The Company accounts for the lease and non-lease components of its leases as a single lease component. Rent expense is recognized on a straight-line basis over the lease term. As a result of this agreement, the Company recognized right-of-use (“ROU”) asset and liability of \$247 pursuant to ASC 842, Leases. Operating lease ROU assets and liabilities are recognized at the lease commencement date based on the present value of lease payments over the lease term. ROU assets represent the Company’s right to use an underlying asset for the lease term and lease liabilities represent the Company’s obligation to make lease payments arising from the lease. Generally, the implicit rate of interest in arrangements is not readily determinable and the Company utilizes its incremental borrowing rate in determining the present value of lease payments. The Company’s incremental borrowing rate is a hypothetical collateralized borrowing rate based on its understanding of what its credit rating would be. The operating lease ROU asset includes any lease payments made and excludes lease incentives.

On February 8, 2022, the Company entered into a copier lease which will end on February 7, 2025. As a result, the Company recognized additional ROU asset and liability of \$13.

As a result of these lease agreements, the Company recognized ROU asset and liability in the aggregate of \$260.

Rent expense related to these leases reflected as part of selling, general and administrative expenses on the Company’s Condensed Consolidated Statements of Operations totaled \$29 and \$88 for the three months and nine months ended September 2023. Rent expense totaled \$29 and \$58 for the three months and nine months ended September 2022.

Other information related to leases and future minimum lease payments under non-cancellable operating leases were as follows:

	September 30, 2023 (Unaudited)	September 30, 2022 (Unaudited)
Cash paid for amounts included in the measurement of lease liabilities:		
Operating cash flows from operating leases	\$ 78	\$ 79
Right-of-use assets obtained in exchange for lease liabilities:		
Operating leases	\$ 87	\$ 260
Weighted-average remaining lease term (in years):		
Operating leases	0.8	2.0
Weighted-average discount rate:		
Operating leases	10%	10%

Future minimum lease payments under non-cancellable operating leases were as follows:

	September 30, 2023 (Unaudited)
Within one year	\$ 95
After one year and within two years	2
Thereafter	-
Total future minimum lease payments	\$ 97
Less – discount	(5)
Lease liability	\$ 92

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 review carefully 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, 2022. 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.

Throughout this Quarterly Report on Form 10-Q, the terms “GTBP,” “we,” “us,” “our,” “the Company” and “our Company” refer to GT Biopharma, Inc., a Delaware corporation, formerly known as Oxis International, Inc., DDI Pharmaceuticals, Inc. and Diagnostic Data, Inc., together with our subsidiaries.

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®”) fusion protein immune cell engager technology platform. Our TriKE® platform generates proprietary therapeutics designed to harness and enhance the cancer killing abilities of a patient's own natural killer cells (“NK cells”). Once bound to an NK cell, our moieties are designed to enhance the NK cell, through induction of NK cell expansion and priming via the cytokine portion, and precisely direct it to one or more specifically targeted proteins expressed on a specific type of cancer cell or virus infected cell, ultimately resulting in the targeted cell's death. TriKE® 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 and solid tumors. 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® may have the ability, if approved for marketing, to be used as both a monotherapy and in combination with other standard-of-care therapies including combinations with off-the-shelf NK cell infusions.

Our initial work has been conducted in collaboration with the Masonic Cancer Center at the University of Minnesota under a program led by Dr. Jeffrey Miller, the Deputy Director. 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.

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 immunoglobulin-like lectin 3) 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. The approval of the CD33 antibody-drug conjugate gemtuzumab validates this targeted approach.

GTB-3550 is being replaced by a more potent next-generation camelid nanobody TriKE®, GTB-3650, targeting relapsed/refractory Acute Myeloid Leukemia (AML) and high-risk Myelodysplastic Syndromes (MDS).

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. We have significant preclinical data to support and concluded preclinical studies, generated a cGMP batch of drug, and are in the process of filing an Investigational New Drug (IND) application in the 2nd half of 2023. The only curative therapy for AML and MDS is transplant, and relapse still occurs in many patients that undergo transplants so novel immunotherapeutic approaches that can be leveraged in this setting are highly desirable. It is also important to note that elderly frail patients cannot receive transplants and thus alternative approaches are needed. 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 these diseases.

GTB-5550

GTB-5550 is a B7-H3 targeted TriKE® which targets B7-H3 on the surface of advanced solid tumors. We are advancing GTB-5550 through preclinical studies and have initiated a GMP manufacturing campaign. We have filed a Pre-IND package with the Food and Drug Administration (FDA) in anticipation of filing an IND application and starting a study targeting patients with B7-H3 positive solid tumors thereafter. B7-H3 expression is expressed in a number of solid tumor settings as well as in multiple myeloma and is not expressed on normal tissues, making it an exciting pan-cancer tumor target. Expression of B7-H3 is also associated with disease progression and bad outcomes in many cancers. Due to these characteristics several clinical trials are ongoing leveraging targeting of B7-H3 in solid tumor. GTB-5550 would be the first modality to target B7-H3 through NK cell immunotherapy and a unique single domain camelid B7-H3. The initial study will be designed as a basket trial, targeting solid tumor malignancies with high expression of B7-H3, including prostate cancer, ovarian cancer, head and neck cancer, lung cancer, and breast cancer.

Economic Disruption

While we make our strategic planning decisions based on the assumption that the markets we are targeting will grow in the long term, our business is dependent, in large part on, and directly affected by, business cycles and other factors affecting the economy generally. Our industry depends on general economic conditions and other factors, including consumer spending and preferences, changes in inflation rates, supply chain issues and impediments should they arise for us, as the U.S. and various other major economies are now experiencing, consumer confidence, fuel costs, fuel availability, environmental impact, governmental incentives and regulatory requirements, and political volatility, especially in cybersecurity growth markets.

In addition, the outbreak of full-scale wars between Russia and Ukraine and Israel and Palestine (“Conflicts”) and global reactions thereto have increased U.S. domestic and global energy prices. Oil supply disruptions related to the Conflicts, and sanctions and other measures taken by the U.S. and its allies, could lead to higher costs for gas, food, and goods in the U.S. and other geographies and exacerbate the inflationary pressures on the worldwide economy, with potentially adverse impacts on our business, results of operations and financial condition.

Results of Operations

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

Research and Development Expenses (“R&D”)

We recorded \$1.36 million and \$2.74 million in research and development expense (“R&D”) for the three months ended September 30, 2023 and 2022, a reduction of \$1.38 million over the prior year comparable period. We recorded \$5.11 million and \$5.79 million in R&D for the nine months ended September 30, 2023 and 2022, a reduction of \$0.68 million over the prior year comparable period. R&D 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. R&D expenses decreased over the previous year primarily due to reduction of in-house staff offset with the increase in compensation to consultants as we prepare to advance our next generation GTB-3650 camelid nanobody product into the clinic.

Selling, General and Administrative Expenses (“S,G&A”)

We recorded \$1.76 million and \$4.28 million in selling, general and administrative expense (“SG&A”) for the three months ended September 30, 2023 and 2022, a decrease of \$2.52 million over the prior year comparable period. We recorded \$5.30 million and \$9.51 million in SG&A for the nine months ended September 30, 2023 and 2022, a reduction of \$4.21 million over the prior year comparable period. The decrease in SG&A is primarily attributable to reduction in stock-based compensation to advisory board, investor relations consultants, legal and professional fees, and payroll expenses.

Interest Income

We recorded interest income of \$0.22 million and \$0.11 million for the three months ended September 30, 2023 and 2022, and \$0.60 million and \$0.15 million for the nine months ended September 30, 2023 and 2022, respectively. The increase in interest income was due to higher interest rates offered by financial institutions in the three months and nine months ended September 30, 2023, as compared to the same comparable periods of 2022.

Interest Expense

We recorded \$0 interest expense for the three months ended September 30, 2023 and 2022, and \$0.21 million and \$0 for the nine months ended September 30, 2023 and 2022, respectively. The increase in interest expense was due to the financing costs incurred associated with the issuance of warrants accounted as warrant liability during the current year, with no such comparable costs in the prior year.

Change in Fair Value of Warrant Liability

We recorded a gain of \$0.49 million and \$0.06 for the three months ended September 30, 2023 and 2022, and \$4.80 million and \$0.08 million for the nine months ended September 30, 2023 and 2022, respectively. The gain was recorded as a result of a change in fair value of warrant liability for the three months and nine months ended September 30, 2023 as compared to the same comparable periods of 2022.

Gain on Extinguishment of Debt

We recorded \$0 gain on extinguishment of debt for the three months ended September 30, 2023 and 2022, respectively, and a gain of \$0.55 million and \$0 for the nine months ended September 30, 2023 and 2022, respectively. The gain in the nine months ended September 30, 2023 resulted due to share settlement of a greater amount of vendor accounts payable than the fair value of the shares on the date of settlement.

Unrealized Gain or Loss on Marketable Securities

We recorded unrealized gains on marketable securities of \$0.01 million and \$0.04 million for the three months and nine months ended September 30, 2023, respectively, compared to unrealized losses of \$0.02 and \$0.05 million for the three and nine months ended September 30, 2022, respectively. This resulted from an improved mix of investments combined with higher interest rates for the three months and nine months ended September 30, 2023 as compared to prior year comparable periods of 2022.

As a result of the above changes, the Company recorded a net loss of \$2.42 million and \$4.70 million for the three months and nine months ended September 30, 2023, as compared to a net loss of \$6.88 million and \$15.30 million for the same comparable periods in 2022.

Liquidity and Capital Resources

The Company's current operations have focused on business planning, raising capital, establishing an intellectual property portfolio, hiring, and conducting preclinical studies. On January 4, 2023, the Company raised \$6.50 million from an institutional investor by selling 3,600,000 shares of common stock, and pre-funded warrants to purchase up to 2,900,000 shares of common stock. 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. We anticipate that cash utilized in the twelve months following this filing date for selling, general and administrative expenses will range between \$3.0 million and \$4.0 million, and research and development expenses will range between \$10.0 million and \$12.0 million.

The Company reported cash and cash equivalents of \$2.65 million and short-term investments of \$13.37 million as of September 30, 2023. Management believes that the Company has sufficient cash and cash equivalents, and short-term investments to funds its operations for more than twelve months from the date of this filing.

Management is currently evaluating different strategies to obtain the required funding for future operations. These strategies may include but are not limited to: public offerings of equity and/or debt securities, payments from potential strategic research and development, licensing and/or marketing arrangements with pharmaceutical companies.

Critical Accounting Policies

We consider the following accounting policies to be critical given they involve estimates and judgments made by management and are important for our investors' understanding of our operating results and financial condition.

Basis of Presentation and Principles of Consolidation

The accompanying condensed consolidated financial statements have been prepared in accordance with accounting principles generally accepted in the United States of America ("GAAP"). These condensed consolidated financial statements include the accounts of the Company and its wholly owned subsidiaries, Oxis Biotech, Inc. and Georgetown Translational Pharmaceuticals, Inc. Intercompany transactions and balances have been eliminated in consolidation.

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 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.

Stock-Based Compensation

The Company accounts for share-based awards to employees, nonemployees, and consultants in accordance with the provisions of ASC 718, "Compensation-Stock Compensation". Stock-based compensation cost is measured at fair value on the grant date and that fair value is recognized as expense over the requisite service, or vesting, period. The Company values its equity awards using the Black-Scholes option pricing model, and accounts for forfeitures when they occur. Use of the Black-Scholes option pricing model requires the input of subjective assumptions including expected volatility, expected term, and a risk-free interest rate. The Company estimates volatility using its own historical stock price volatility. The expected term of the instrument is estimated by using the simplified method to estimate expected term. The risk-free interest rate is estimated using comparable published federal funds rates.

Inflation

We believe that inflation has not had a material adverse impact on our business or operating results during the periods presented other than the impact of inflation on the general economy. However, there is a risk that the Company's operating costs could become subject to inflationary pressures in the future, which would have the effect of increasing the Company's operating costs, and which would put additional stress on the Company's working capital resources.

Off-balance Sheet Arrangements

We have no off-balance sheet arrangements as of September 30, 2023.

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, 2023. Based on that evaluation, we have concluded that our disclosure controls and procedures were effective as of September 30, 2023.

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 generally accepted accounting principles 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 the assets of the Company
- Provide reasonable assurance that transactions are recorded as necessary to permit preparation of consolidated financial statements in accordance with generally accepted accounting principles, and that receipts and expenditures of the company are being made only in accordance with authorizations of management and directors of the company; and
- Provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use or disposition of the company's assets that could have a material effect on the consolidated financial statements.

All internal control systems, no matter how well designed, have inherent limitations and can provide only reasonable, not absolute, assurance that the objectives of the control system 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 all control systems, no evaluation of controls can provide absolute assurance that all control issues and instances of fraud, if any, within our company have been detected. Therefore, even those systems determined to be effective can provide only reasonable assurance with respect to financial statement preparation and presentation.

As of September 30, 2023, our management, including our interim Chief Executive Officer and Chief Financial Officer conducted an assessment of the effectiveness of the Company's internal control over financial reporting. In making this assessment, we used the criteria set forth by the Committee of Sponsoring Organizations of the Treadway Commission in internal control integrated framework. Based upon our evaluation, we concluded that our internal controls over financial reporting were operating effectively with a significant level of precision as of September 30, 2023.

Changes in Internal Control Over Financial Reporting

Except for the ongoing remediation of previously disclosed material weaknesses in internal controls over financial reporting, no changes in our internal control 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

On May 11, 2023, our former interim Chief Executive Officer, Dr. Greg Berk, filed a complaint with the Occupational Safety and Health Administration alleging retaliation against him during his tenure at the Company for raising concerns related to the public disclosure of certain product timelines. The Company is vigorously defending this matter and believe it to be without merit. 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.

On May 13, 2022, the Company made a claim against Michael Handelman, its former Chief Financial Officer, asserting that he misappropriated Company funds and shares of common stock, and failed to file the required SEC reports on Form 3 and Form 4 regarding each acquisition and disposition of the Company's common stock. The Company seeks monetary damages estimated at \$0.37 million; the return of shares of our common stock received without authorization and the disgorgement of any profits earned from the sale of those shares; a full accounting for all sums charged on the Company's debit card, with payment to the Company for any charges that cannot be demonstrated to have a corporate purpose; an order directing Mr. Handelman to make all filings required by Section 16(a) of the 1934 Act; an award of all sums and shares improperly issued to members of Mr. Handelman's family; and an award of the Company's attorneys' fees and any forum and arbitration fees. As a component of Mr. Handelman's contract with the Company, disputes shall be fully addressed and finally resolved by binding arbitration conducted by the American Arbitration Association (AAA) in New York City, New York, in accordance with its National Employment Dispute Resolution rules. In connection with any such arbitration, the Company shall bear all costs not otherwise borne by a plaintiff in a court proceeding. The Company agrees that any decisions of the arbitration panel will be binding and enforceable in any state in which the Company conducts the operation of its business. In accordance with California Labor Laws, the Company has designated Los Angeles, California as the venue for this arbitration. The claims have been heard by an arbitrator in Los Angeles and the decision of the arbitrator is currently pending. Mr. Handelman has not asserted any counterclaims against the Company.

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 has recently dismissed without prejudice its Complaint before the California Superior Court of Los Angeles. The Company also recently 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. The Company believes that TWF's claims are without merit and will continue to defend vigorously against these claims.

Item 6. Exhibits

Exhibit	Description	Filed Herewith	Form	Number	SEC File No.	Filing Date
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	Amended and Restated Bylaws of GT Biopharma, Inc. effective November 3, 2022.		8-K	3.1	01-40023	11/09/2022
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	04/04/2019
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
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 1, 2023

By: /s/ Manu Ohri

Manu Ohri

Chief Financial Officer and 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 1, 2023

By: /s/ Michael Breen

Name: Michael Breen

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

CERTIFICATION PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT

I, Manu Ohri, 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 1, 2023

By: /s/ Manu Ohri

Name: Manu Ohri

Title: Chief Financial Officer and 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, Interim 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, 2023 (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 1, 2023

By: /s/ Michael Breen

Name: Michael Breen

Title: Interim Chief Executive Officer,
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, Manu Ohri, 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, 2023 (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 1, 2023

By: /s/ Manu Ohri

Name: Manu Ohri

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