

**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 June 30, 2022.

☐ 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)

N/A

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

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 August 15, 2022, the issuer had 31,092,498 shares of common stock outstanding.

GT Biopharma, Inc. and Subsidiaries
Table of Contents

	<u>Page</u>
PART I – FINANCIAL INFORMATION	
Item 1. Financial Statements	
Condensed Consolidated Balance Sheets as of June 30, 2022 (Unaudited) and December 31, 2021	3
Condensed Consolidated Statements of Operations for the three months and six months ended June 30, 2022 and 2021 (Unaudited)	4
Condensed Consolidated Statements of Stockholders' Equity (Deficit) (Unaudited)	5
Condensed Consolidated Statements of Cash Flows for the three months and six months ended June 30, 2022 and 2021 (Unaudited)	7
Condensed Notes to Consolidated Financial Statements (Unaudited)	8
Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations	19
Item 3. Quantitative and Qualitative Disclosures About Market Risks	21
Item 4. Controls and Procedures	21
PART II – OTHER INFORMATION	
Item 1. Legal Proceedings	22
Item 6. Exhibits	22
SIGNATURES	23

GT BIOPHARMA, INC AND SUBSIDIARIES
CONDENSED CONSOLIDATED BALANCE SHEETS
(in thousands, except shares and par value)

	June 30, 2022	December 31, 2021
	(Unaudited)	
ASSETS		
Current assets		
Cash and cash equivalents	\$ 5,358	\$ 8,968
Short-term investments	18,367	23,011
Prepaid expenses and other current assets	222	190
Total current assets	<u>23,947</u>	<u>32,169</u>
Operating lease right-of-use asset	214	-
Deposits	9	-
TOTAL ASSETS	<u>\$ 24,170</u>	<u>\$ 32,169</u>
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities		
Accounts payable	\$ 7,263	\$ 8,220
Accrued expenses	1,129	1,901
Current operating lease liability	103	-
Derivative liability	115	138
Total current liabilities	<u>8,610</u>	<u>10,259</u>
Non-current operating lease liability	120	-
Total liabilities	<u>8,730</u>	<u>10,259</u>
Stockholders' equity		
Convertible Preferred stock, par value \$0.01, 15,000,000 shares authorized		
Series C – 96,230 shares issued and outstanding at June 30, 2022 and December 31, 2021, respectively	1	1
Common stock, par value \$0.001, 750,000,000 shares authorized, 30,693,558 shares and 32,061,989 shares issued and outstanding as of June 30, 2022 and December 31, 2021, respectively	31	32
Common stock issuable 0 shares and 327,298 shares at June 30, 2022 and December 31, 2021, respectively	-	1,113
Additional paid in capital	677,411	674,348
Accumulated deficit	(662,003)	(653,584)
Total stockholders' equity	<u>15,440</u>	<u>21,910</u>
TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY	<u>\$ 24,170</u>	<u>\$ 32,169</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		For the six months ended	
	June 30,		June 30,	
	2022	2021	2022	2021
	(Unaudited)	(Unaudited)	(Unaudited)	(Unaudited)
Revenues	\$ -	\$ -	\$ -	\$ -
Operating Expenses:				
Research and development	1,139	639	3,226	2,279
Selling, general and administrative (including \$463 and \$577 expense from stock compensation granted to officers and directors during the three months ended June 30, 2022 and 2021, and \$910 and \$14,873 for the six months ended June 30, 2022 and 2021, respectively)	1,875	3,742	5,230	31,104
Loss from Operations	3,014	4,381	8,456	33,383
Other (Income) Expense				
Interest income	(36)	-	(44)	-
Interest expense	-	-	-	696
Change in fair value of derivative liability	(5)	480	(23)	459
Unrealized loss on marketable securities	6	-	30	-
Total Other (Income) Expense	(35)	480	(37)	1,155
Net Loss	\$ (2,979)	\$ (4,861)	\$ (8,419)	\$ (34,538)
Net loss per share - basic and diluted	\$ (0.10)	\$ (0.15)	\$ (0.26)	\$ (1.39)
Weighted average common shares outstanding - basic and diluted	31,237,560	33,516,428	31,865,425	24,925,908

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 June 30, 2022 (Unaudited)

	<u>Preferred Shares</u>		<u>Common Shares</u>		<u>Common Shares Issuable</u>		<u>Additional Paid in Capital</u>	<u>Accumulated Deficit</u>	<u>Total</u>
	<u>Shares</u>	<u>Amount</u>	<u>Shares</u>	<u>Amount</u>	<u>Shares</u>	<u>Amount</u>			
Balance, March 31, 2022	96	\$ 1	32,346	\$ 32	-	\$ -	\$ 676,780	\$ (659,024)	\$ 17,789
Cancellation of common stock upon settlement with former officer	-	-	(1,845)	(1)	-	-	(222)	-	(223)
Equity compensation to officers, employees, and board of directors	-	-	79	-	-	-	463	-	463
Issuance of common shares for services	-	-	114	-	-	-	390	-	390
Net loss	-	-	-	-	-	-	-	(2,979)	(2,979)
Balance, June 30, 2022	96	\$ 1	30,694	\$ 31	-	\$ -	\$ 677,411	\$ (662,003)	\$ 15,440

For the six months ended June 30, 2022 (Unaudited)

	<u>Preferred Shares</u>		<u>Common Shares</u>		<u>Common Shares Issuable</u>		<u>Additional Paid in Capital</u>	<u>Accumulated Deficit</u>	<u>Total</u>
	<u>Shares</u>	<u>Amount</u>	<u>Shares</u>	<u>Amount</u>	<u>Shares</u>	<u>Amount</u>			
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- conversion of notes payable	-	-	327	-	(327)	(1,113)	1,113	-	-
Equity compensation to officers, employees, and board of directors	-	-	164	-	-	-	910	-	910
Issuance of common shares for services	-	-	277	-	-	-	1,262	-	1,262
Net loss	-	-	-	-	-	-	-	(8,419)	(8,419)
Balance, June 30, 2022	96	\$ 1	30,694	\$ 31	-	\$ -	\$ 677,411	\$ (662,003)	\$ 15,440

For the three months ended June 30, 2021 (Unaudited)

	<u>Preferred Shares</u>		<u>Common Shares</u>		<u>Common Shares Issuable</u>		<u>Additional Paid in Capital</u>	<u>Accumulated Deficit</u>	<u>Total</u>
	<u>Shares</u>	<u>Amount</u>	<u>Shares</u>	<u>Amount</u>	<u>Shares</u>	<u>Amount</u>			
Balance, March 31, 2021	96	\$ 1	20,517	\$ 21	7,634	\$ 25,956	\$ 623,287	\$ (625,248)	\$ 24,017
Common shares issued upon mandatory conversion of notes payable and accrued interest	-	-	4,482	4	(4,482)	(15,240)	15,232	-	(4)
Common shares issued upon exercise of warrants	-	-	2,954	3	-	-	16,232	-	16,235
Issuance of common stock for services	-	-	92	-	-	-	327	-	327
Equity compensation to officers and board of directors	-	-	99	-	-	-	577	-	577
Net loss	-	-	-	-	-	-	-	(4,861)	(4,861)
Balance, June 30, 2021	96	\$ 1	28,144	\$ 28	3,152	\$ 10,716	\$ 655,655	\$ (630,109)	\$ 36,291

For the six months ended June 30, 2021 (Unaudited)

	<u>Preferred Shares</u>		<u>Common Shares</u>		<u>Common Shares Issuable</u>		<u>Additional Paid in Capital</u>	<u>Accumulated Deficit</u>	<u>Total</u>
	<u>Shares</u>	<u>Amount</u>	<u>Shares</u>	<u>Amount</u>	<u>Shares</u>	<u>Amount</u>			
Balance, December 31, 2020	2,450	3	5,218	5	-	-	566,356	(595,797)	(29,433)
Extinguishment of debt discount upon adoption of ASU 2020-06	-	-	-	-	-	-	(4,745)	226	(4,519)
Conversion of Preferred Series J-1 to common stock	(2,354)	(2)	692	1	-	-	1	-	-
Common shares issued upon mandatory conversion of notes payable and accrued interest	-	-	8,261	8	3,152	10,716	28,075	-	38,799
Common shares issued upon exercise of warrants	-	-	3,049	3	-	-	16,293	-	16,296
Issuance of common stock in public offering, net of cost	-	-	4,945	5	-	-	24,674	-	24,679
Issuance of common stock for research and development agreement	-	-	190	-	-	-	1,355	-	1,355
Issuance of common stock for services	-	-	2,050	2	-	-	8,777	-	8,779
Equity compensation to officers and board of directors	-	-	3,739	4	-	-	14,869	-	14,873
Net loss	-	-	-	-	-	-	-	(34,538)	(34,538)
Balance, June 30, 2021	96	\$ 1	28,144	\$ 28	3,152	\$ 10,716	\$ 655,655	\$ (630,109)	\$ 36,291

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 six months ended	
	June 30,	
	2022 (Unaudited)	2021 (Unaudited)
CASH FLOWS FROM OPERATING ACTIVITIES		
Net loss	\$ (8,419)	\$ (34,538)
Adjustments to reconcile net loss to net cash (used in) operating activities:		
Stock based compensation – consultants and research and development	1,262	10,134
Stock based compensation – officers, employees and board of directors	910	14,873
Convertible notes payable issued for consulting services	-	720
Change in fair value of derivative liability	(23)	459
Change in operating lease right-of-use assets	46	-
Unrealized loss on marketable securities	30	-
Changes in operating assets and liabilities:		
(Increase) decrease in prepaid expenses	(32)	302
(Increase) in deposits	(9)	-
(Decrease) in accounts payable and accrued expenses	(1,729)	(611)
(Decrease) in operating lease liability	(37)	-
Increase in accrued interest	-	689
Net Cash (Used in) Operating Activities	<u>(8,001)</u>	<u>(7,972)</u>
CASH FLOWS FROM INVESTING ACTIVITIES		
Sales of short term investments	4,614	-
Net Cash Provided By Investing Activities	<u>4,614</u>	<u>-</u>
CASH FLOWS FROM FINANCING ACTIVITIES		
Proceeds from issuance of common stock	-	24,679
Cancellation of common stock upon settlement with former officer	(223)	-
Proceeds from exercise of warrants	-	16,296
Proceeds from issuance of notes payable	-	1,205
Net Cash (Used in) Provided by Financing Activities	<u>(223)</u>	<u>42,180</u>
Net (Decrease) Increase in Cash	(3,610)	34,208
Cash at Beginning of Period	8,968	5,297
Cash at End of Period	<u>\$ 5,358</u>	<u>\$ 39,505</u>
<u>SUPPLEMENTAL DISCLOSURES OF CASH FLOW INFORMATION:</u>		
Cash paid during the period for:		
Interest	\$ -	\$ -
Income taxes	\$ -	\$ -
<u>SUPPLEMENTAL DISCLOSURES OF NON-CASH INVESTING AND FINANCING ACTIVITIES</u>		
Recognition of operating lease right-of-use assets and related lease liabilities	\$ 260	\$ -
Extinguishment of unamortized debt discount and adjustment to accumulated deficit upon adoption of ASU 2020-06	\$ -	\$ 4,745
Common stock issued upon conversion of notes payable and accrued interest	\$ -	\$ 38,799
Convertible notes payable issued for accrued expenses	\$ -	\$ 1,525

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
June 30, 2022 and 2021
(Unaudited)

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 immuno-oncology products based on our proprietary Tri-specific Killer Engager (TriKE®) fusion protein immune cell engager technology platform. The Company's TriKE® platform generates proprietary therapeutics designed to harness and enhance the cancer killing abilities of a patient's own natural killer cells, or NK cells. Once bound to an NK cell, our moieties are designed to enhance the NK cell, and precisely direct it to one or more specifically targeted proteins expressed on a specific type of cancer cell or virus infected cell, resulting in the targeted cell's death. TriKE®s can be designed to target any number of tumor antigens on hematologic malignancies or solid tumors and do not require patient-specific customization.

Note 2 – Summary of Significant Accounting Policies

Basis of Presentation and Principles of Consolidation

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

The accompanying condensed consolidated financial statements are unaudited. These unaudited interim condensed consolidated financial statements have been prepared in accordance with accounting principles generally accepted in the United States of America ("GAAP") and applicable rules and regulations of the Securities and Exchange Commission ("SEC") regarding interim financial reporting. Certain information and note disclosures normally included in the financial statements prepared in accordance with GAAP have been condensed or omitted pursuant to such rules and regulations. Accordingly, these interim condensed consolidated financial statements should be read in conjunction with the consolidated financial statements and notes thereto contained in the Company's Annual Report on Form 10-K for the fiscal year ended December 31, 2021 filed with the SEC on March 28, 2022 (the "2021 Annual Report"). The consolidated balance sheets as of December 31, 2021 included herein were derived from the audited consolidated financial statements as of that date.

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

Liquidity

The accompanying consolidated financial statements have been prepared under the assumption that the Company will continue as a going concern. Such assumption contemplates the realization of assets and satisfaction of liabilities in the normal course of business. For the six months ended June 30, 2022, the Company recorded a net loss of \$8.4 million and used cash in operations of \$8.0 million. As of June 30, 2022, the Company had a cash and short-term investments balance of \$23.7 million, working capital of \$15.3 million and stockholders' equity of \$15.4 million. Management anticipates that the \$23.7 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 quarter ended June 30, 2022 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.

COVID-19

In March 2020, the World Health Organization declared coronavirus COVID-19 a global pandemic. This contagious disease outbreak, which has continued to spread, has adversely affected workforces, customers, economies, and financial markets globally. It has also disrupted the normal operations of many businesses. This outbreak could adversely affect the Company's operations.

While the pandemic has impacted the Company's operations, during the six months ended June 30, 2022, the Company believes the COVID-19 pandemic had limited impact on its operating results. The Company has not observed any impairments of its assets or a significant change in the fair value of its assets due to the COVID-19 pandemic. At this time, it is not possible for the Company to predict the duration or magnitude of the adverse results of the outbreak and its effects on the Company's business or results of operations, financial condition, or liquidity.

The Company has been following the recommendations of health authorities to minimize exposure risk for its team members, including having team members work remotely. Most vendors have transitioned to electronic submission of invoices and payments.

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 derivative liabilities, valuation of equity instruments issued for 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. As of June 30, 2022 total cash and cash equivalents, which consist of cash and money market funds, amounted to approximately \$5.4 million.

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 businesses. Investments are carried at fair value with the unrealized holding gains and losses reported in the accompanying condensed consolidated statements of operations. As of June 30, 2022 total short-term investments amounted to approximately \$18.4 million.

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 derivative liability of \$115,000 at June 30, 2022 and \$138,000 at December 31, 2021 was based on Level 2 measurements.

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

Derivative Financial Instruments

The Company evaluates its financial instruments to determine if such instruments are derivatives or contain features that qualify as embedded derivatives. For derivative financial instruments that are accounted for as liabilities, the derivative instrument is initially recorded at its fair value and is then re-valued at each reporting date, with changes in the fair value reported in the consolidated statements of operations. The classification of derivative instruments, including whether such instruments should be recorded as liabilities or as equity, is evaluated at the end of each reporting period. Derivative instrument liabilities are classified in the balance sheet as current or non-current based on whether or not net-cash settlement of the derivative instrument could be required within 12 months of the balance sheet date. The fair value of the embedded derivatives 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 expenses. Purchased materials that do not have an alternative future use are also expensed.

Leases

The Company accounts for its leases in accordance with Accounting Standards Update ("ASU") No. 2016-02, *Leases* (Topic 842) ("ASC 842"). ASC 842 requires lessees to (i) recognize a right of use asset ("ROU asset") and a lease liability that is measured at the present value of the remaining lease payments, on the consolidated balance sheets, (ii) recognize a single lease cost, calculated over the lease term on a straight-line basis, and (iii) classify lease related cash payments within operating and financing activities. The Company has made an accounting policy election to not recognize short-term leases on the consolidated balance sheets and all non-lease components, such as common area maintenance, were excluded. At any given time during the lease term, the lease liability represents the present value of the remaining lease payments, and the ROU asset is measured as the amount of the lease liability, adjusted for pre-paid rent, unamortized initial direct costs, and the remaining balance of lease incentives received. Both the lease ROU asset and liability are reduced to zero at the end of the lease term.

The Company leases office space and equipment. At the lease inception date, the Company determines if an arrangement is, or contains a lease. Some of the Company's leases include options to renew at similar terms. The Company assesses these options to determine if the Company is reasonably certain of exercising these options based on relevant economic and financial factors. Options that meet these criteria are included in the lease term at the lease commencement date.

During the period ended June 30, 2022, the Company executed lease agreements for its office space and equipment and as a result, recorded operating lease right-of-use assets and the related lease liabilities of \$260,000 pursuant to ASC 842, *Leases* (see Note 8).

Net Earnings (Loss) Per Share

Basic earnings (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 earnings (loss) per share is computed using the weighted-average number of common shares and the dilutive effect of contingent shares outstanding during the period. Potentially dilutive contingent shares, which primarily consist of convertible notes, 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:

	June 30, 2022 (Unaudited)	June 30, 2021 (Unaudited)
Options to purchase common stock	302,500	-
Warrants to purchase common stock	2,337,274	2,365,473
Unvested restricted common stock	488,429	-
Convertible Series C Preferred Stock	-	7
Total anti-dilutive securities	3,128,203	2,365,480

Concentration

Cash is deposited in one financial institution. The balances held at this financial institution at times may be in excess of Federal Deposit Insurance Corporation ("FDIC") insurance limits of up to \$250,000.

The Company has a significant concentration of expenses incurred and accounts payable from a single vendor. Please see Note 4 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 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 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 is effective for all entities for fiscal years beginning after December 15, 2021, including interim periods within those fiscal years. An entity should apply the guidance provided in ASU 2021-04 prospectively to modifications or exchanges occurring on or after the effective date. Early adoption is permitted for all entities, including adoption in an interim period. 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.

In November 2021, the FASB issued ASU 2021-10, *Government Assistance (Topic 832)—Disclosures by Business Entities about Government Assistance*. ASU 2021-10 increases the transparency of government assistance including the disclosure of (1) the types of assistance, (2) an entity's accounting for the assistance, and (3) the effect of the assistance on an entity's financial statements. The ASU is effective for fiscal years beginning after December 15, 2021. The Company adopted this ASU as of January 1, 2022 on a prospective basis. The adoption of this standard did not have any material impact on the Company's financial statements.

Other recent accounting pronouncements issued by the FASB, including its Emerging Issues Task Force, the American Institute of Certified Public Accountants, and the Securities and Exchange Commission (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 (in thousands):

June 30, 2022 (Unaudited)				
	Cost	Unrealized Gains	Unrealized Losses	Fair Value
Short-term investments	\$ 18,397	\$ —	\$ (30)	\$ 18,367
Total	\$ 18,397	\$ —	\$ (30)	\$ 18,367

December 31, 2021				
	Cost	Unrealized Gains	Unrealized Losses	Fair Value
Short-term investments	\$ 23,040	\$ —	\$ (29)	\$ 23,011
Total	\$ 23,040	\$ —	\$ (29)	\$ 23,011

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

June 30, 2022 (Unaudited)				
	Fair Value	Level 1	Level 2	Level 3
Money market funds	\$ 5,339	\$ 5,339	\$ —	\$ —
Corporate notes and commercial paper	18,367	—	18,367	—
Total financial assets	\$ 23,706	\$ 5,339	\$ 18,367	\$ —

December 31, 2021				
	Fair Value	Level 1	Level 2	Level 3
Money market funds	\$ 5,484	\$ 5,484	\$ —	\$ —
Corporate notes and commercial paper	23,011	—	23,011	—
Total financial assets	\$ 28,495	\$ 5,484	\$ 23,011	\$ —

As of June 30, 2022, the fair value of the derivative liability amounted to \$115,000. The details of derivative liability transactions for the six months ended June 30, 2022 and 2021, are as follows:

	Three Months Ending		Six Months Ending	
	June 30, 2022 (Unaudited)	June 30, 2021 (Unaudited)	June 30, 2022 (Unaudited)	June 30, 2021 (Unaudited)
Beginning Balance	\$ 120,000	\$ 362,000	\$ 138,000	\$ 383,000
Fair value upon issuance of warrants	—	—	—	—
Change in fair value	\$ (5,000)	\$ 480,000	\$ (23,000)	\$ 459,000
Extinguishment	—	—	—	—
Ending Balance	\$ 115,000	\$ 842,000	\$ 115,000	\$ 842,000

Note 4 – Accounts Payable

Accounts payable consisted of the following (in thousands):

	June 30, 2022 (Unaudited)	December 31, 2021
Accounts payable to a third-party manufacturer	\$ 6,440	\$ 5,056
Other accounts payable	823	3,164
Total accounts payable	\$ 7,263	\$ 8,220

The Company relies on a third-party contract manufacturing operation to produce and/or test our compounds used in our potential product candidates. The Company's accounts payable to this vendor were \$6.4 million as of June 30, 2022 and \$5.1 million as of December 31, 2021.

Note 5 – Convertible Notes Payable

Notes Payable Issued for Cash

As part of the Company's financing activities, the Company issued convertible notes payable totaling \$25.3 million between August 1, 2018 and January 26, 2021. On February 16, 2021, in accordance with the terms of the note agreements upon completion of the equity offering, these notes were mandatorily converted at a conversion rate of \$3.40 per share into 7,438,235 shares of the Company's common stock.

Notes Payable Issued for Settlement Agreements

In fiscal 2019 and 2020, the Company issued its convertible notes payable in the amount of \$2.5 million to resolve claims and disputes pertaining to certain debt and equity instruments issued by the Company in prior years. On February 16, 2021 in accordance with the note agreements upon completion of the equity offering, these notes were mandatorily converted at a conversion rate of \$3.40 per share into 743,529 shares of the Company's common stock.

Notes Payable Issued for Forbearance Agreements

On June 23, 2020, the Company entered into Standstill and Forbearance Agreements (collectively, the "Forbearance Agreements") with the holders of \$13.2 million aggregate principal amount of the Convertible Notes (the "Default Notes"), which were in default. Pursuant to the Forbearance Agreements, the holders of the Default Notes agreed to forbear from exercising their rights and remedies under the Default Notes (including declaring such Default Notes (together with any default amounts and accrued and unpaid interest) immediately due and payable) until the earlier of (i) the date that the Company completes a future financing in the amount of \$15 million and, in connection therewith, commences listing on NASDAQ (collectively, the "New Financing") or (ii) January 31, 2021 (the "Termination Date").

On February 16, 2021 in accordance with the note agreements upon completion of the equity offering, these notes, in the amount of \$3.8 million, were mandatorily converted at a conversion rate of \$3.40 per share into 1,132,059 shares of the Company's common stock.

Notes Payable issued for Consulting Agreements

In prior years, the Company issued its convertible notes payable in exchange for consulting services in the amount of \$1.6 million.

On February 16, 2021 in accordance with the note agreements upon completion of the equity offering, these notes in the aggregate amount of \$1.6 million were mandatorily converted at a conversion rate of \$3.40 per share into 472,059 shares of the Company's common stock.

Notes Payable issued for Accrued Interest

In prior years, the Company recorded accrued interest of \$5.6 million related to all notes payable. On February 16, 2021, in accordance with the note agreements upon completion of the equity offering, the accrued interest was mandatorily converted at a conversion rate of \$3.40 per share into 1,627,440 shares of the Company's common stock. The Company did not incur interest expense for the three months and six months ended June 30, 2022, and \$0 and \$0.7 million for the three months and six months ended June 30, 2021.

Adoption of ASU 2020-06

In fiscal 2020, the Company recorded a note/debt discount of \$4.7 million to account for the beneficial conversion feature that existed on the date of issuance for the above convertible notes payable. The debt discount was being amortized to interest expense over the term of the corresponding convertible notes payable.

On January 1, 2021 the Company chose to adopt ASU 2020-06, Debt-Debt with Conversion and Other Options (Subtopic 470-20) and Derivatives and Hedging-Contracts in Entity's Own Equity (Subtopic 815-40): Accounting for Convertible Instruments and Contracts in an Entity's Own Equity. As a result of the adoption of ASU 2020-06, the Company extinguished the previously recorded debt discount of \$4.7 million by charging the opening additional paid in capital at January 1, 2021. In addition, the Company also adjusted accumulated deficit to account for the derecognition of the \$0.2 million interest expense due to the amortization of the debt discount that was recorded in fiscal 2020. As a result of these adjustments, the unamortized debt discount of \$4.5 million was extinguished.

Note 6 – Derivative Liability

During the year ended December 31, 2020, the Company issued certain warrants that contained a fundamental transaction provision that could give rise to an obligation to pay cash to the warrant holder upon occurrence of certain change in control type events. In accordance with ASC 480, the fair value of 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 statement of operations.

The derivative liabilities were valued using a Binomial pricing model with the following average assumptions:

	June 30, 2022	December 31, 2021
	(Unaudited)	
Stock Price	\$ 2.99	\$ 3.05
Risk-free interest rate	2.99%	1.26%
Expected volatility	118%	129%
Expected life (in years)	3.1	3.6
Expected dividend yield	-	-
Fair Value of Warrants	<u>\$ 115,000</u>	<u>\$ 138,000</u>

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 derivative securities was determined by the remaining contractual life of the derivative 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.

The Company recognized a gain of \$5,000 and \$23,000 to account for the change in fair value of the derivative liability between the reporting periods for the three months and six months ended June 30, 2022.

The Company recognized an expense of \$480,000 and \$459,000 to account for the change in the fair value of the derivative liability between the reporting periods for the three months and six months ended June 30, 2021.

Note 7 – Stockholders' Equity

The Company's authorized capital as of June 30, 2022 was 750,000,000 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

Common Stock Issuable

On February 16, 2021, as a result 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 issuable at December 31, 2021 valued at \$1.1 million, were issued during the six months period ended June 30, 2022.

Cancellation of common stock

During the six months ended June 30, 2022, the Company cancelled and returned to authorized capital 290,999 previously issued shares of common stock.

Equity compensation to officers, employees and directors

As part of employment agreements with its former CEO and its former CFO ("Officers"), the Officers received a fully vested stock grant equal to an aggregate of 10% and 1.5% of the fully diluted shares of common stock of the Company (calculated with the inclusion of the current stock holdings of the CEO) upon conversion of options, warrants and Convertible Notes in association with a national markets qualified financing as consideration for entering into the Agreement (with such stock to vest and be delivered within 30 days after the national markets qualified financing). In addition, the Company also granted similar equity compensation to members of the Company's directors wherein these directors received stock grants equal to 1% and 1.25% of the fully diluted shares of common stock of the Company. Pursuant to the agreement, approximately 33% of the common stock to be issued vested immediately while the remaining 67% vests over a period of two years.

On February 16, 2021, the Company completed its equity offering and listed its shares of common stock on the Nasdaq Capital Market. As such, 4,379,407 shares of its common stock were granted to these Officers, employees and directors, which had a fair value of \$18.6 million. Since the grant of the common stock is subject to milestone or performance conditions, the Company measured the fair value of the common stock on the respective date of the agreement, and such awards were recorded as compensation expense as the milestone or performance condition is met and in accordance with its vesting terms.

During the period ended June 30, 2022, the Company recognized \$783,000 of stock compensation expense related to vesting of shares to officers and directors. The fair value of the remaining 213,268 unvested shares of common stock to officers, employees and directors at June 30, 2022 was \$1.0 million and will be recognized as stock compensation expense in future periods pursuant to its vesting term.

During the period ended June 30, 2021, the Company recognized \$14.9 million of stock compensation expense related to vesting of shares to officers and directors.

Issuance of common shares for services

As part of consulting agreements with certain consultants, the Company agreed to grant these consultants common stock equal to 1% and 3% of the fully diluted shares of common stock of the Company upon conversion of options, warrants and Convertible Notes in association with a national markets qualified financing as consideration for entering into the Agreement (with such stock to vest and be delivered within 30 days after the national markets qualified financing).

On February 16, 2021, the Company completed its equity offering and listed its shares of common stock on the Nasdaq Capital Market. As a result of this offering, the Company agreed to issue to these consultants 2,850,090 shares of common stock with a grant date fair value of \$10.7 million, of which 1,934,817 shares of common stock vested immediately while the remaining 915,273, shares of common stock vests over two years. Pursuant to current accounting guidelines, as the grant of the common stock is subject to milestone or performance conditions, the Company measured the fair value of the common stock on the respective date of the agreement, and then such award is being recorded as compensation expense based upon the vesting term of the grant.

During the three months and six months ended June 30, 2021, the Company recognized stock compensation expense of \$327,000 and \$8.5 million related to the issuance and vesting of 2,050,060 shares of common stock issued to consultants for services.

During the three months and six months ended June 30, 2022, the Company recognized \$390,000 and \$1.3 million of stock compensation expense related to the issuance and vesting of 277,156 shares of common stock issued to consultants for services in fiscal 2022.

As of June 30, 2022, there are a total of 275,161 unvested shares of common stock to consultants with a fair value of \$941,000 that will be recognized as stock compensation expense in future periods based upon its vesting term.

Settlement of common stock with a former Officer

On April 29, 2022, the Company entered into a settlement agreement with its former Chief Executive Officer (“Officer”) and received 1,845,000 shares of its previously issued common stock in full and final settlement of all its claims against the Officer. The common stock was subsequently cancelled. In addition, the Company incurred legal and professional expenses of \$223,000. Pursuant to current accounting guidelines, this amount was accounted as costs of the acquisition of the common stock and recorded as a reduction to additional paid in capital. Both the Company and the Officer released each other from claims under the settlement agreement.

Preferred Stock

Series C Preferred Stock

At June 30, 2022 and December 31, 2021, there were 96,230 shares of series C preferred stock, par value \$0.01 per share (the “Series C Preferred Stock”) issued and outstanding.

As a result of reverse stock splits in previous years and the agreement terms for adjusting the rights of the related shares, the 96,230 shares of Series C Preferred Stock are not currently convertible, have no voting rights, and in the event of liquidation, the holders of the Series C Preferred Stock would not participate in any distribution of the assets or surplus funds of the Company. The holders of Series C Preferred Stock also are not currently entitled to any dividends if and when declared by the Company’s board of directors (the “Board”). No dividends to holders of the Series C Preferred Stock were issued or unpaid through June 30, 2022 and 2021, respectively.

Series K Preferred Stock

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

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

As of June 30, 2022 and December 31, 2021, there were no shares of Series K Preferred stock issued and outstanding.

Warrants and Options

Common Stock Warrants

Stock warrant transactions for the six months ended June 30, 2022:

	Number of Warrants	Weighted Average Exercise Price
Outstanding at December 31, 2021:	2,337,274	\$ 5.30
Granted	-	-
Forfeited/canceled	-	-
Exercised	-	-
Warrants outstanding at June 30, 2022	2,337,274	\$ 5.30
Warrants exercisable at June 30, 2022	2,337,274	\$ 5.30

As of June 30, 2022, all issued and outstanding warrants are fully vested, and have no intrinsic value as the exercise price of these warrants was greater than the market price.

Common Stock Options

Stock option transactions for the six months ended June 30, 2022:

	Number of Options	Weighted Average Exercise Price
Options outstanding at December 31, 2021:	302,500	\$ 3.05
Granted	-	-
Forfeited/canceled	-	-
Exercised	-	-
Options outstanding at June 30, 2022	302,500	\$ 3.05
Options exercisable at June 30, 2022	141,306	\$ 3.05

During the period ended June 30, 2022, the Company recorded stock compensation of \$127,000 to account for the fair value of stock options that vested. At June 30, 2022, there were 161,194 unvested options with a grant date fair value of \$430,710 which will be recognized as stock compensation in future periods based upon the remaining vesting term of the applicable grants.

There was no intrinsic value of the outstanding options as of June 30, 2022 as the exercise price of these options was greater than the market price.

Note 8 – Commitments and Contingencies

Litigation

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

On August 28, 2019, a complaint was filed in the Superior Court of California, County of Los Angeles, West Judicial District, Santa Monica Courthouse, Unlimited Civil Division by Jeffrey Lion, an individual (“Lion”), and by Daniel Vallera, an individual (“Vallera”). Lion and Vallera are referred to jointly as the “Plaintiffs.” The complaint was filed against GT Biopharma, Inc. and its subsidiary Oxis Biotech, Inc. (either of them or jointly, the “Company”). The Plaintiffs alleged breach of a license agreement between the Plaintiffs and the Company entered into on or about September 3, 2015. A settlement of the case was reached on February 7, 2022 in the amount of \$425,000. This amount was fully accrued at December 31, 2021. The settlement amount was subsequently paid on March 4, 2022.

Significant Agreements

Research and Development Agreements

- a. The Company is a party to a scientific research agreement with the Regents of the University of Minnesota, 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. The term of this agreement shall expire on June 30, 2023.

The University of Minnesota shall use reasonable efforts to complete the project for a fixed sum of \$2.1 million. For the three months and six months ended June 30, 2022, the Company recorded an expense of \$192,000 and \$383,000, respectively, relating to scientific research agreement.

- b. On October 5, 2020, GT Biopharma 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 signed five Statements of Work for the research and development of products for use in clinical trials. At June 30, 2022, the Company’s commitments in relation to these Statements of Work and any related Change Orders totaled approximately \$13.0 million, of which \$9.8 million was incurred at that date and an additional \$3.2 million is in process during fiscal year 2022.

For the three months and six months ended June 30, 2022, the Company recorded an expense of \$92,000 and \$1,180,000, respectively, relating to the Master Service 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 \$0.2 million, and an annual License Maintenance fee of \$0.1 million 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 \$0.25 million 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.

For the three months and six months ended June 30, 2022, the Company did not incur any research and development expense relating to the 2016 Exclusive Patent License Agreement.

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 \$5,000 beginning in 2022, 2.5% to 5% royalty fees, or minimum annual royalty payments of \$0.25 million 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.

For the three months and six months ended June 30, 2022, the Company did not incur any research and development expense relating to 2021 Patent License Agreement.

Lease Agreements

On November 19, 2021 the Company entered into a sublease with Aimmune Therapeutics, Inc. for 4,500 square feet of office space located in Brisbane, California having a commencement date of January 1, 2022 and maturing on June 30, 2024. Additionally, on February 8, 2022, the Company entered into a lease of a photocopier, which matures on February 7, 2025.

Rent expense related to these leases reflected on the Company's Condensed Consolidated Statements of Operations totaled \$29,000 and \$58,000 for the three months and six months ended June 30 2022, respectively.

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

	June 30, 2022 (Unaudited)
Cash paid for amounts included in the measurement of lease liabilities:	
Operating cash flows from operating leases	\$ 49,000
Right-of-use assets obtained in exchange for lease liabilities:	
Operating leases	\$ 260,000
Weighted-average remaining lease term (in years):	
Operating leases	2.25
Weighted-average discount rate:	
Operating leases	10%

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

	Operating leases (Unaudited)
2022 (6 months)	\$ 59,000
2023	121,000
2024	66,000
Total future minimum lease payments	\$ 246,000
Less – discount	(29,000)
Lease liability	<u>\$ 217,000</u>

Note 9 - Subsequent Events

On July 15, 2022, the Compensation Committee of the Board (the "Committee") authorized the grant of stock awards or stock options, as applicable, to acquire shares of common stock under the Company's 2022 Omnibus Incentive Plan. As a result, the Company granted stock options to consultants, employees, officers and directors to purchase an aggregate of 1,532,952 shares of common stock. The stock options are exercisable at \$2.48 per share, vest over a four-year period, will expire in ten years from the grant date and have an estimated fair value of \$3.4 million. In addition, the Company also granted an aggregate of 398,940 fully vested shares of common stock to consultants and certain officers with a fair value of \$989,000 for services.

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, 2021. 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 off 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, or NK cells. Once bound to an NK cell, our moieties are designed to enhance the NK cell, and precisely direct it to one or more specifically targeted proteins expressed on a specific type of cancer cell or virus infected cell, ultimately resulting in the targeted cell's death. TriKE[®] can be designed to target any number of tumor antigens on hematologic malignancies, sarcomas 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, sarcoma and solid tumors. The platform is scalable, and we are putting processes in place to be able to produce IND-ready moieties in a timely manner after a specific TriKE[®] conceptual design. After conducting market and competitive research, specific moieties can then be advanced into the clinic on our own or through potential collaborations with larger companies. We are also evaluating, in conjunction with our Scientific Advisory Board, additional moieties designed to target different tumor antigens. We believe our TriKE[®] may have the ability, if approved for marketing, to be used as a monotherapy, augment the current monoclonal antibody therapeutics, be used in conjunction with more traditional cancer therapy and potentially overcome certain limitations of current chimeric antigen receptor, or CAR-T, therapy.

We are also using our TriKE[®] platform to develop therapeutics useful for the treatment of infectious disease such as for the treatment of patients infected by the human immunodeficiency virus (HIV). While the use of anti-retroviral drugs has substantially improved the health and increased the longevity of individuals infected with HIV, these drugs are designed to suppress virus replication to help modulate progression to AIDS and to limit further transmission of the virus. Despite the use of anti-retroviral drugs, infected individuals retain reservoirs of latent HIV-infected cells that, upon cessation of anti-retroviral drug therapy, can reactivate and re-establish an active HIV infection. For a curative therapy, destruction of these latent HIV infected cells must take place. The HIV- TriKE[®] contains the antigen binding fragment (Fab) from a broadly neutralizing antibody targeting the HIV-Env protein. The HIV- TriKE[®] is designed to target HIV while redirecting NK cell killing specifically to actively replicating HIV infected cells. The HIV- TriKE[®] induced NK cell proliferation, and demonstrated the ability in vitro to reactivate and kill HIV-infected T-cells. These findings indicate a potential role for the HIV- TriKE[®] in the reactivation and elimination of the latently infected HIV reservoir cells by harnessing the NK cell's ability to mediate the antibody-directed cellular cytotoxicity (ADCC).

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 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.

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 hostilities between Russia and Ukraine and global reactions thereto have increased U.S. domestic and global energy prices. Oil supply disruptions related to the Russia-Ukraine conflict, 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 Six Months Ended June 30, 2022 and 2021

Research and Development Expenses

We recorded \$1.1 million and \$0.6 million in research and development expense (“R&D”) for the three months ended June 30, 2022 and 2021, an increase of \$0.5 million over the prior year comparable period. We recorded \$3.2 million and \$2.3 million in R&D for the six months ended June 30, 2022 and 2021, an increase of \$0.9 million over the prior year comparable period. The increase in R&D resulted primarily resulted due to hiring of additional employees and professionals in 2022 and costs associated with the continued development and manufacturing of our most advanced TriKE® product candidates GTB-3650 and GTB-5550.

Selling, general and administrative expenses

We recorded \$1.9 million and \$3.7 million in selling, general and administrative expense (“SG&A”) for the three months ended June 30, 2022 and 2021, a decrease of \$1.8 million over the prior year comparable period. We recorded \$5.2 million and \$31.1 million in SG&A for the six months ended June 30, 2022 and 2021, a decrease of \$25.9 million over the prior year comparable period. The decrease in S,G&A resulted primarily due to a decrease in stock-based compensation to consultants, officers and directors. We recorded additional expenses during the three months and six months ended June 30, 2021 that consisted of legal, finance, consulting and professional fees in support of our planned growth and new public company compliance initiatives.

Interest Income

We recorded interest income of \$0.04 million and \$0 for the three months ended June 30, 2022 and 2021, and \$0.04 million and \$0 for the six months ended June 30, 2022 and 2021, respectively. The increase in interest income is due to the interest earned on short-term investments in the three months and six months ended June 30, 2022 as compared to the same comparable periods of 2021.

Interest Expense

We recorded no interest expense for the three months ended June 30, 2022 and 2021, and \$0 and \$0.7 million for the six months ended June 30, 2022 and 2021, respectively. The decrease in interest expense is due to the conversion of convertible notes payable to common shares during 2021. The Company did not have any outstanding convertible notes payable as of and during the three months and six months periods ended June 30, 2022.

Change in fair value of derivative liability

The change in fair value of derivative liability due to fair value remeasurement resulted in a gain of \$0.01 million and a loss of \$0.5 million for the three months ended June 30, 2022 as compared to a gain of \$0.02 million and a loss of \$0.5 million for the same comparable periods ending June 30, 2021.

Unrealized loss on marketable securities

The unrealized loss on marketable securities was \$0.01 million and \$0.03 million for the three months and six months ended June 30, 2022, as compared to \$0 and \$0 for the three months and six months ended June 30, 2021.

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. The Company does not have any product candidates approved for sale and has not generated any revenue from product sales. The Company has sustained operating losses since inception and expects such losses to continue over 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 \$5 and \$6 million and research and development expenses will range between \$14 and \$16 million.

The Company reported cash and cash equivalents of \$5.4 million, and short-term investments of \$18.4 million as of June 30, 2022. 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 grants, licensing and/or marketing arrangements with other 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. 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 Generally Accepted Accounting Principles 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 derivative 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.

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 June 30, 2022.

Item 3. Quantitative and Qualitative Disclosures About Market Risk

This 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 June 30, 2022. Based on that evaluation, we have concluded that our disclosure controls and procedures were not effective as of June 30, 2022 as a result of material weaknesses in internal control over financial reporting due to (i) inadequate segregation of duties, (ii) risks of executive override and (iii) insufficient written policies and procedures for accounting and financial reporting with respect to the requirements and application of both U.S. GAAP and SEC regulation, in each case, as described in "Item 9A. Controls and Procedures" in the Company's Form 10-K for the year ended December 31, 2021.

The Company has begun to take measures to mitigate the issues identified and implement a functional system of internal controls over financial reporting. Specifically, the Company has brought on board an experienced Chief Financial Officer, and retained the services of outside consultants to review the Company's bank records, transactions with affiliates and/or related parties, expense reimbursement practices and vendor payment practices. In addition, the Company's board of directors previously designated a Special Committee in August 2021 charged with, among other duties, evaluating the current compliance, compensation, operations and personnel of the Company, and determining actions appropriate to address any deficiencies or inefficiencies identified through such evaluation. The Special Committee completed its assigned directives on April 29, 2022. The directives included measures that included or will include, but not be limited to, hiring of additional employees in the Company's accounting department; preparation of risk-control matrices to identify key risks and develop and document policies to mitigate those risks; and identification and documentation of standard operating procedures for key financial activities, with additional oversight by the Company's board of directors.

Changes in Internal Control over Financial Reporting

Except for the ongoing remediation of the material weaknesses in internal controls over financial reporting noted above, 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 April 29, 2022, the Company entered into a settlement agreement with its former Chief Executive Officer (“Officer”) and received 1,845,000 shares of its previously issued common stock in full and final settlement of all its claims against the Officer. The common stock was subsequently cancelled. Both the Company and the Officer released each other from claims under the settlement agreement.

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		DEF 14A		001-40023	4/29/2022
3.6	Bylaws, as restated effective September 7, 1994 and as amended through April 29, 2003		10-QSB	3	000-08092	8/14/2003
4.1	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 Financial Officer and Chief Financial 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 Financial Officer and Chief Financial 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: August 15, 2022

By: /s/ Manu Ohri

Manu Ohri

Chief Financial 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: August 15, 2022

By: /s/ Michael Breen

Name: Michael Breen

Title: Interim Chief Executive Officer,
Chairman and Director

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: August 15, 2022

By: /s/ Manu Ohri

Name: Manu Ohri

Title: Chief Financial Officer and Principal Accounting 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 June 30, 2022 (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: August 15, 2022

By: /s/ Michael Breen

Name: Michael Breen

Title: Interim Chief Executive Officer,
Chairman and Director

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 June 30, 2022 (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: August 15, 2022

By: /s/ Manu Ohri

Name: Manu Ohri

Title: Chief Financial Officer and Principal Accounting Officer
