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, 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	**94-1620407**
(State or other jurisdiction of incorporation or organization)	**(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

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 October 31, 2022, the issuer had 32,557,720 shares of common stock outstanding.

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

	September 30 2022 (Unaudited)	December 31, 2021
ASSETS		
Current Assets		
Cash and cash equivalents	$ 2,465	$ 8,968
Short-term investments	18,319	23,011
Prepaid expenses and other current assets	88	190
Total Current Assets	20,872	32,169
Operating lease right-of-use asset	190	-
Deposits	9	-
TOTAL ASSETS	$ 21,071	$ 32,169
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current Liabilities		
Accounts payable	$ 3,325	$ 8,220
Accrued expenses	1,537	1,901
Current operating lease liability	106	-
Derivative liability	57	138
Total Current Liabilities	5,025	10,259
Non-current operating lease liability	92	-
Total Liabilities	5,117	10,259
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, 2022 and December 31, 2021, respectively	1	1
Common stock, par value $0.001, 250,000,000 shares authorized, 32,507,618 shares and 32,061,989 shares issued and outstanding as of September 30, 2022 and December 31, 2021, respectively	33	32
Common stock issuable zero shares and 327,298 shares at September 30, 2022 and December 31, 2021, respectively	-	1,113
Additional paid in capital	684,804	674,348
Accumulated deficit	(668,884)	(653,584)
Total Stockholders' Equity	15,954	21,910
TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY	$ 21,071	$ 32,169

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,	
	2022	2021	2022	2021
	(unaudited)	(unaudited)	(unaudited)	(unaudited)
Revenues	$ -	$ -	$ -	$ -
Operating Expenses				
Research and development (includes $201 and $0 of expense from stock compensation to officers, employees and directors vesting during the three months ended September 30, 2022 and 2021, and $327 and $0 for the nine months ended September 30, 2022 and 2021, respectively)	2,743	1,008	5,969	3,287
Selling, general and administrative (includes $2,743 and $577 of expense from stock compensation granted to officers, employees and directors during the three months ended September 30, 2022 and 2021, and $3,527 and $15,450 for the nine months ended September 30, 2022 and 2021, respectively)	4,280	4,946	9,510	36,050
Loss from Operations	7,023	5,954	15,479	39,337
Other (Income) Expense				
Interest income	(107)	(32)	(151)	(32)
Interest expense	-	-	-	696
Change in fair value of derivative liability	(58)	(502)	(81)	(43)
Unrealized loss on marketable securities	23	33	53	33
Total Other (Income) Expense	(142)	(501)	(179)	654
Net Loss	$ (6,881)	$ (5,453)	$ (15,300)	$ (39,991)
Net loss per share – basic and diluted	$ (0.22)	$ (0.17)	$ (0.48)	$ (1.54)
Weighted average common shares outstanding – basic and diluted	31,380,634	31,381,282	31,723,792	25,945,827

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, 2022 (Unaudited)

	Preferred Shares		Common Shares		Common Shares Issuable		Additional Paid in	Accumulated	
	Shares	Amount	Shares	Amount	Shares	Amount	Capital	Deficit	Total
Balance, June 30, 2022	96	$ 1	30,694	$ 31	-	$ -	$ 677,411	$ (662,003)	$ 15,440
Equity compensation to officers, employees, and board of directors	-	-	456	1	-	-	2,943	-	2,944
Equity compensation to consultants	-	-	135	-	-	-	1,200	-	1,200
Issuance of common shares in settlement of vendor payable	-	-	1,222	1	-	-	3,250	-	3,251
Net loss	-	-	-	-	-	-	-	(6,881)	(6,881)
Balance, September 30, 2022	96	$ 1	32,507	$ 33	-	$ -	$ 684,804	$ (668,884)	$ 15,954

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

	Preferred Shares		Common Shares		Common Shares Issuable		Additional Paid	Accumulated	
	Shares	Amount	Shares	Amount	Shares	Amount	in Capital	Deficit	Total
Balance, December 31, 2021	96	$ 1	32,062	$ 32	327	$ 1,113	$ 674,348	$ (653,584)	$ 21,910
Cancellation of common stock previously issued for services	-	-	(291)	-	-	-	-	-	-
Cancellation of common stock previously issued to prior CEO	-	-	(1,845)	(1)	-	-	(222)	-	(223)
Common stock issued upon conversion of notes payable	-	-	327	-	(327)	(1,113)	1,113	-	-
Equity compensation to officers, employees, and board of directors	-	-	620	1	-	-	3,853	-	3,854
Equity compensation to consultants	-	-	412	-	-	-	2,462	-	2,462
Issuance of common shares in settlement of vendor payable	-	-	1,222	1	-	-	3,250	-	3,251
Net loss	-	-	-	-	-	-	-	(15,300)	(15,300)
Balance, September 30, 2022	96	$ 1	32,507	$ 33	-	$ -	$ 684,804	$ (668,884)	$ 15,954

For The Three Months Ended September 30, 2021 (Unaudited)

	Preferred Shares		Common Shares		Common Shares Issuable		Additional Paid in	Accumulated	
	Shares	Amount	Shares	Amount	Shares	Amount	Capital	Deficit	Total
Balance, June 30, 2021	96	$ 1	28,144	$ 28	3,152	$ 10,716	$ 655,655	$ (630,109)	$ 36,291
Common shares issued upon mandatory conversion of notes payable and accrued interest	-	-	2,147	2	(2,148)	(7,300)	7,294	-	(4)
Common shares issued upon exercise of warrants	-	-	26	-	-	-	138	-	138
Issuance of common stock for services	-	-	93	-	-	-	327	-	327
Equity compensation to officers and board of directors	-	-	98	-	-	-	577	-	577
Net loss	-	-	-	-	-	-	-	(5,453)	(5,453)
Balance, September 30, 2021	96	$ 1	30,508	$ 30	1,004	$ 3,416	$ 663,991	$ (635,562)	$ 31,876

For The Nine Months Ended September 30, 2021 (Unaudited)

	Preferred Shares		Common Shares		Common Shares Issuable		Additional Paid in	Accumulated	
	Shares	Amount	Shares	Amount	Shares	Amount	Capital	Deficit	Total
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	-	-	10,409	10	1,004	3,416	35,373	-	38,799
Common shares issued upon exercise of warrants	-	-	3,074	3	-	-	16,430	-	16,433
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	-	-	2,142	2	-	-	9,101	-	9,103
Equity compensation to officers and board of directors	-	-	3,838	4	-	-	15,446	-	15,450
Net loss	-	-	-	-	-	-	-	(39,991)	(39,991)
Balance, September 30, 2021	96	$ 1	30,508	$ 30	1,004	$ 3,416	$ 663,991	$ (635,562)	$ 31,876

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 31,	
	2022	**2021**
	(Unaudited)	**(Unaudited)**
CASH FLOWS FROM OPERATING ACTIVITIES		
Net loss	$ (15,300)	$ (39,991)
Adjustments to reconcile net loss to net cash used in operating activities:		
Stock based compensation – consultants	2,462	10,458
Stock based compensation - officers, employees and board of directors	3,854	15,450
Convertible notes payable issued for consulting services	-	720
Change in fair value of derivative liability	(81)	(43)
Change in operating lease right-of-use assets	70	-
Unrealized loss on marketable securities	53	-
Changes in operating assets and liabilities:		
Decrease in prepaid expenses	102	279
(Increase) in deposits	(9)	-
(Decrease) Increase in accounts payable and accrued expenses	(2,008)	537
(Decrease) in operating lease liability	(62)	-
Increase in accrued interest	-	689
Net Cash (Used in) Operating Activities	(10,919)	(11,901)
CASH FLOWS FROM INVESTING ACTIVITIES		
Sales (purchases) of investments	4,639	(26,031)
Net Cash Provided by (Used in) Investing Activities	4,639	(26,031)
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	-	16,433
Proceeds from issuance of notes payable	-	1,205
Net Cash (Used in) Provided by Financing Activities	(223)	42,317
Net (Decrease) Increase in Cash	(6,503)	4,385
Cash at Beginning of Period	8,968	5,297
Cash at End of Period	$ 2,465	$ 9,682
SUPPLEMENTAL DISCLOSURES OF CASH FLOW INFORMATION		
Cash paid during the year for:		
Interest	$ -	$ -
Income taxes paid	$ -	$ -
SUPPLEMENTAL DISCLOSURES OF NON-CASH INVESTING AND FINANCING ACTIVITIES		
Right-of-use assets exchanged for 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
Common stock issued upon settlement of vendor payable	$ 3,251	$ -
Convertible notes payable issued for accrued expenses	$ -	$ 1,525

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

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 a natural killer ("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 sheet as of December 31, 2021 included herein was derived from the audited consolidated financial statements as of that date.

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

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 nine months ended September 30, 2022, the Company recorded a net loss of $15.3 million and used cash in operations of $10.9 million. As of September 30, 2022, the Company had a cash and short-term investments balance of $20.8 million, working capital of $15.8 million and stockholders' equity of $16.0 million. Management anticipates that the $20.8 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 September 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 nine months ended September 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 September 30, 2022, total cash and cash equivalents which consist of cash and money market funds, amounted to approximately $2.5 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 September 30, 2022, total short-term investments amounted to approximately $18.3 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 $57,000 at September 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, non-employees 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. 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 nine months ended September 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 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 common 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, 2022 (Unaudited)	**September 30, 2021 (Unaudited)**
Options to purchase common stock	1,835,452	-
Warrants to purchase common stock	2,337,274	2,337,274
Unvested restricted common stock	295,588	-
Convertible Series C Preferred Stock	-	7
Total anti-dilutive securities	4,468,314	2,337,281

Concentration

Cash is deposited in one financial institution. The balances held at this financial institution at times may be more than 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"*. 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. The adoption of this standard 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 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 (in thousands):

	September 30, 2022 (Unaudited)			
	Cost	Unrealized Gains	Unrealized Losses	Fair Value
Short-term investments	$ 18,372	$ —	$ (53)	$ 18,319
Total	$ 18,372	$ —	$ (53)	$ 18,319

	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):

	September 30, 2022 (Unaudited)			
	Fair Value	Level 1	Level 2	Level 3
Money market funds	$ 2,319	$ 2,319	$ —	$ —
Corporate notes and commercial paper	18,319	18,319	—	—
Total financial assets	$ 20,638	$ 20,638	$ —	$ —

	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	$ 28,495	$ —	$ —

As of September 30, 2022, the fair value of the derivative liability was $57,000. The details of derivative liability transactions for the nine months ended September 30, 2022 and 2021, are as follows:

	Three Months Ending		Nine Months Ending	
	September 30, 2022 (Unaudited)	September 30, 2021 (Unaudited)	September 30, 2022 (Unaudited)	September 30, 2021 (Unaudited)
Beginning balance	$ 115,000	$ 842,000	$ 138,000	$ 383,000
Issuance of warrants	—	—	—	—
Change in fair value	$ (58,000)	$ (502,000)	$ (81,000)	$ (43,000)
Extinguishment	—	—	—	—
Ending balance	$ 57,000	$ 340,000	$ 57,000	$ 340,000

Note 4 – Accounts Payable

Accounts payable consisted of the following (in thousands):

	September 30, 2022 (Unaudited)	December 31, 2021
Accounts payable to a third-party manufacturer	$ 2,636	$ 6,335
Other accounts payable	689	1,885
Total accounts payable	$ 3,325	$ 8,220

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

On August 24, 2022, the Company entered into an agreement with this third-party manufacturer and issued 1,222,281 shares of common stock with a fair value of $3.3 million as part of a payment agreement. The shares were valued at $2.66 based on the closing price of the Company's common stock on the date of the agreement. As part of the agreement, the Company also paid this third-party manufacturer $1.3 million on September 1, 2022 and $1.0 million on October 3, 2022, respectively, and agreed to pay another $1.0 million in November 2022. In addition, the Company and the third-party manufacturer agreed that services to be rendered in future periods, as specified in the agreement, will be paid or settled at the Company's discretion, in a combination of cash and issuance of the Company's common stock. The agreement also amended certain agreements executed in prior years which eliminated future financial commitment of the Company.

The Company's accounts payable to this third-party manufacturer amounted to $2.6 million and $6.3 million as of September 30, 2022 and December 31, 2021, respectively.

Note 5 – Convertible Notes Payable

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 of certain 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:

	September 30, 2022 (Unaudited)	December 31, 2021
Stock price	$ 1.76	$ 3.05
Risk-free interest rate	4.25%	1.26%
Expected volatility	114%	129%
Expected life (in years)	2.8	3.6
Expected dividend yield	-	-

Fair value of warrants	$ 57,000	$ 138,000

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 expected volatility. The expected life was determined by using 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 $58,000 and $81,000 to account for the change in fair value of the derivative liability between the reporting periods for the three months and nine months ended September 30, 2022.

The Company recognized a gain of $502,000 and $43,000 to account for the change in the fair value of the derivative liability between the reporting periods for the three months and nine months ended September 30, 2021.

Note 7 – Stockholders' Equity

The Company's authorized capital as of September 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. The Company subsequently changed its authorized shares of common stock to 250,000,000 shares (see Note 9).

Common Stock

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 issuable at December 31, 2021 valued at $1.1 million, were issued during the nine months ended September 30, 2022.

Cancellation of common stock

The Company cancelled 290,999 previously issued shares of common stock during the nine months ended September 30, 2022.

Equity compensation to officers, employees and directors

a. 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 board of 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 was met and in accordance with its vesting terms.

   During the three months and nine months ended September 30, 2022, the Company recognized $382,000 and $1.1 million of stock compensation expense related to the vesting of common shares to officers, employees and directors.

   During the three months and nine months ended September 30, 2021, the Company recognized $577,000 and $15.4 million of stock compensation expense related to the vesting of these common shares to officers, employees and directors.

b. In July 2022, the Company granted 378,058 shares of fully vested common stock with a fair value of $938,000 to certain officers of the Company for services rendered.

   During the three months and nine months ended September 30, 2022, the Company recognized $938,000 and $938,000 of stock compensation expense related to the vesting of these common shares.

c. During the three months and nine months ended September 30, 2022, the Company also recognized stock compensation expense of $1.6 million and $1.8 million, respectively, to account for the fair value of vested stock options.

As a result, the Company recognized total stock compensation expense of $2.9 million and $3.8 million for the three months and nine months ended September 30, 2022.

As of September 30, 2022, there were 134,836 unvested shares of common stock issued to officers, employees and directors with a fair value of $626,000 that will be recognized as stock compensation expense in future periods pursuant to its vesting term.

Equity compensation to consultants

a. 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 nine months ended September 30, 2022, the Company recognized stock compensation expense of $325,000 and $976,000, respectively, related to the vesting of these common shares to consultants.

b. In July 2022, the Company granted 20,882 shares of fully vested common stock with a fair value of $52,000 to certain consultants for services rendered. This was recognized as stock compensation expense for the three months and nine months ending September 30, 2022.

   During the three months and nine months ended September 30, 2022, the Company recognized $64,000 and $675,000 of stock compensation expense related to the vesting of common shares.

c. During the three months and nine months ended September 30, 2022, the Company also recognized stock compensation expense of $759,000 and $759,000, respectively, to account for the fair value of all vested stock options.

As a result, the Company recognized total stock compensation expense of $1.2 million and $2.5 million during the three and nine months ended September 30, 2022, respectively.

During the three months and nine months ended September 30, 2021, the Company recognized an aggregate of $327,000 and $9.1 million of stock compensation expense related to the vesting of common shares granted to consultants.

As of September 30, 2022, there were 160,752 unvested shares of common stock issued to consultants with a fair value of $552,000 that will be recognized as stock compensation expense in future periods based upon their 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 September 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 September 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 a on an as-converted-to-common stock basis, in any distribution to holders of the Company's common stock.

As of September 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 nine months ended September 30, 2022 were as follows:

	Number of Warrants	Weighted Average Exercise Price
Warrants outstanding at December 31, 2021	2,337,274	$ 5.30
Granted	-	-
Forfeited/cancelled	-	-
Exercised	-	-
Warrants outstanding at September 30, 2022	2,337,274	$ 5.30
Warrants exercisable at September 30, 2022	2,337,274	$ 5.30

As of September 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

Common stock option transactions for the nine months ended September 30, 2022 were as follows:

	Number of Options	Weighted Average Exercise Price
Options outstanding at December 31, 2021	302,500	$ 3.05
Granted	1,532,952	2.48
Forfeited/cancelled	-	-
Exercised	-	-
Options outstanding at September 30, 2022	1,835,452	$ 2.57
Options exercisable at September 30, 2022	1,209,847	$ 2.56

On July 15, 2022, the Company granted certain consultants, employees, officers and directors stock options to purchase an aggregate of 1,532,952 shares of common stock. The stock options are exercisable at $2.48 with a vesting term over a period of 5 months up to 36 months, will expire in ten years from grant date and with an estimated fair value of $3.4 million using the Black Scholes Option pricing model. The Company is recognizing the corresponding stock compensation expense of these options based upon the vesting term. During the three months and nine months ended September 30, 2022, the Company recognized stock compensation expense relating to the vesting of these options of $2.3 million and $2.3 million, respectively.

At September 30, 2022, there were 625,605 unvested options with a grant date fair value of $1.5 million 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, 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. Other than the item discussed below, 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 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 Company's common stock. The Company seeks monetary damages estimated at $370,000; the return of shares of 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 Michael 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 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 that 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 is awaiting to receive a date of hearing from AAA.

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 ("UoMN"), 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 good manufacturing practice ("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 investigational new drug ("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 UoMN/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, of which $924,000 was incurred and recorded in prior years.

   For the three months and nine months ended September 30, 2022, the Company recorded an expense of $192,000 and $575,000 relating to scientific research agreement as compared to $541,000 and $541,000 for the same comparable periods in 2021.

   At September 30, 2022, the Company's remaining commitments in relation to this agreement amounted to approximately $601,000.

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. The Company's commitments in relation to these Statements of Work and any related Change Orders totaled approximately $13 million, of which $10.5 million was incurred and recorded in prior years.

   For the three months and nine months ended September 30, 2022, the Company recorded an expense of $720,000 and $1.9 million, relating to the Master Service Agreement as compared to $528,000 and $677,000 for the same comparable periods in 2021.

   As a result of an amendment to the agreement dated August 24, 2022, the Company has no remaining commitments in relation to these Statements of Work and any related Change Orders (see Note 4).

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, 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 nine months ended September 30, 2022, the Company incurred $90,000 and $313,000 of patent expense relating to the 2016 Exclusive Patent License Agreement. For the three months and nine months ended September 30, 2021 the Company incurred $67,000 and $339,000 of patent expense related to this 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 nine months ended September 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 a third party for approximately 4,500 square feet of office space located in Brisbane, California, at a monthly rent of $9,450, with 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, at a monthly rent of $415, 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 $87,000 for the three months and nine months ended September 30, 2022.

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

		September 30, 2022 (Unaudited)
Cash paid for amounts included in the measurement of lease liabilities:		
Operating cash flows from operating leases	$	79,000
Right-of-use assets obtained in exchange for lease liabilities:		
Operating leases	$	260,000
Weighted-average remaining lease term (in years):		
Operating leases		2.0
Weighted-average discount rate:		
Operating leases		10%

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

		Operating leases (Unaudited)
Within one year	$	121,000
After one year and within two years		94,000
After two years and within three years		2,000
Total future minimum lease payments	$	217,000
Less – discount		(19,000)
Lease liability	$	198,000

Note 9 - Subsequent Events

On October 3, 2022, the Company issued 50,102 shares of common stock with a fair value of $93,000 to an officer of the Company as settlement of debt.

On October 10, 2022, at a special meeting of the stockholders of the Company, the stockholders ratified and approved the inclusion of discretionary votes by brokers and other nominees holding shares for beneficial owners in the tabulation of votes on the proposal presented at the Company's annual meeting of stockholders to reduce the authorized number of shares of the Company's common stock from 750,000,000 shares to 250,000,000 shares.

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

CAUTIONARY NOTICE REGARDING FORWARD-LOOKING STATEMENTS

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

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. 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 Nine Months Ended September 30, 2022 and 2021

Research and Development Expenses

We recorded $2.8 million and $1.0 million in research and development expense ("R&D") for the three months ended September 30, 2022 and 2021, an increase of $1.8 million over the prior year comparable period. We recorded $5.9 million and $3.3 million in R&D for the nine months ended September 30, 2022 and 2021, an increase of $2.6 million over the prior year comparable period. The increase in R&D resulted primarily 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 $4.3 million and $4.9 million in selling, general and administrative expense ("SG&A") for the three months ended September 30, 2022 and 2021, a decrease of $0.6 million over the prior year comparable period. We recorded $9.5 million and $36.1 million in SG&A for the nine months ended September 30, 2022 and 2021, a decrease of $26.6 million over the prior year comparable period. The decrease in SG&A resulted primarily due to a decrease in stock-based compensation to consultants, officers and directors. We recorded additional expenses during the nine months ended September 30, 2021 that consisted of legal, finance, business advisory, consulting and professional fees in support of our planned growth and new public company compliance initiatives.

Interest Income

We recorded interest income of $107,000 and $32,000 for the three months ended September 30, 2022 and 2021, and $151,000 and $32,000 for the nine months ended September 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 nine months ended September 30, 2022 as compared to the same comparable periods of 2021.

Interest Expense

We recorded $0 interest expense for the three months ended September 30, 2022 and 2021, and $0 and $696,000 for the nine months ended September 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 nine months periods ended September 30, 2022.

Change in fair value of derivative liability

The change in fair value of derivative liability was due to fair value remeasurement which resulted in a gain of $58,000 and $502,000 for the three months ending September 30, 2022 and 2021, respectively. The Company recorded a gain of $81,000 for the nine months ended September 30, 2022 compared to a gain of $43,000 for nine months ending September 30, 2021.

Unrealized loss on marketable securities

The unrealized loss on marketable securities was due to fair value remeasurement of our marketable securities which resulted in a loss of $23,000 and $33,000 for the three months ended September 30, 2022 and September 30, 2021, and $53,000 and $33,000 for the nine months ended September 30, 2022 and 2021, respectively.

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 $4 million and $5 million, and research and development expenses will range between $13 million and $15 million.

The Company reported cash and cash equivalents of $2.5 million, and short-term investments of $18.3 million as of September 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. All 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 September 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 September 30, 2022. Based on that evaluation, we have concluded that our disclosure controls and procedures were not effective as of September 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 continued 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 accounting practices, 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 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 Company's common stock. The Company seeks monetary damages estimated at $370,000; the return of shares of 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 Michael 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 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 that the Company conducts the operation of its business. In accordance with California Labor Laws, GT Biopharma has designated Los Angeles, California as the venue for this arbitration. The Company is awaiting to receive a date of hearing from AAA.

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
10.1	Settlement and Investment Agreement dated August 24, 2022, by and between GT Biopharma, Inc. and Cytovance Biologics, Inc.+	X				
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.

\+ The Registrant has omitted portions of this exhibit that are both not material and the type of information that the Registrant treats as private or confidential.

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: October 31, 2022

By: */s/ Manu Ohri*
Manu Ohri
Chief Financial Officer

Exhibit 10.1

The Registrant has excluded certain exhibits that are both not material and constitute the type of information that the Registrant treats as private or confidential.

SETTLEMENT AND INVESTMENT AGREEMENT

BETWEEN

CYTOVANCE BIOLOGICS, INC.

AND

GT BIOPHARMA, INC.

DATED AS OF

AUGUST 24, 2022

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List of Exhibits
Exhibit A – Initial Closing Cross Receipt and Acknowledgement
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Exhibit C – Change Orders
Exhibit D – Outstanding Invoices
Schedule 1 – Definitions

SETTLEMENT AND INVESTMENT AGREEMENT

THIS SETTLEMENT AND INVESTMENT AGREEMENT (this "Agreement") is made and entered into as of August 24, 2022 (the "Signing Date") by and between Cytovance Biologics, Inc., a Delaware corporation ("Cytovance"), and GT Biopharma, Inc., a Delaware corporation ("GTBP"). Certain capitalized terms used but not defined herein shall have the meanings set forth on Schedule 1 attached hereto.

RECITALS

A. Cytovance and GTBP entered into a Master Services Agreement for the performance of various biologic development and manufacturing services with an effective date of October 5, 2020 (the "MSA").

B. Pursuant to the MSA, Cytovance and GTBP entered into five (5) Scopes of Work for the manufacturing process and analytical method transfer activities necessary to manufacture five (5) TriKE products for Phase I clinical trials (collectively, the "SOWs").

C. Three (3) of the five (5) SOWs allow GTBP to pay Cytovance in shares of GTBP Common Stock, subject to certain payment terms as set forth therein (the "Payment Terms").

D. Cytovance and GTBP disagree about the intent, meaning, and application of the Payment Terms, which resulted in a contractual dispute between the parties regarding the Payment Terms and a stoppage of work under the SOWs.

E. Pursuant to the MSA, Cytovance and GTBP entered into dispute resolution to resolve their contractual dispute regarding the Payment Terms and have reached a settlement of their contractual dispute.

F. Cytovance and GTBP have agreed to the following settlement terms: (i) Cytovance will resume work under two (2) of the SOWs and all other documentation relevant thereto to enable GTBP to file its Investigational New Drug ("IND") application with the U.S. Food and Drug Administration (the "FDA") with respect to its GTB-3650 product no later than March 31, 2023 (inclusive of the thirty (30)-day stability run) and with respect to its GTB-5550 product no later than June 30, 2023 (inclusive of the thirty (30)-day stability run), provided that all materials are available and there are no supply chain disruptions, delays attributable to GTBP, or other delays outside of Cytovance's control; (ii) regarding past due invoices and invoices already issued but not yet due, GTBP will pay all amounts due fifty percent (50%) in cash and fifty percent (50%) in shares of GTBP Common Stock; and (iii) regarding future invoices, subject to the terms and conditions of this Agreement, GTBP will pay (a) all materials invoices one hundred percent (100%) in cash, (b) all stability milestone invoices paid one hundred (100%) in cash up to an aggregate of $100,000 and the remaining amounts paid in shares of GTBP Common Stock, and (c) all other invoices and amounts due fifty percent (50%) in cash and fifty percent (50%) in shares of GTBP Common Stock.

G. Cytovance acknowledges and agrees that Cytovance's performance of and adherence to the terms of this Agreement, all SOWs, and all Change Orders, including but not limited to any deliverable timelines, are essential for GTBP's IND applications with the FDA and

any delay in delivery caused by and within the control of Cytovance would be detrimental to the business of GTBP. Accordingly, time is of the essence on Cytovance's performance under this Agreement, SOWs, and any Change Orders. To ensure that Cytovance meets the deadlines set forth in Recital F above with respect to the IND applications for the GTB-3650 and GTB-5550 products, Cytovance and GTBP agree to each designate a project manager and/or technical lead who will jointly establish a timeline for work related to meeting the deadlines set forth above with respect to the IND applications for the GTB-3650 and GTB-5550 products who will regularly meet and discuss the status and progress of the work.

H. In furtherance of the foregoing: (i) Cytovance and GTBP agree to execute the two Change Orders in Exhibit C and any additional Change Orders required to incorporate into the SOWs the revised payment terms and the production schedule detailing the timeline for each deliverable as described in Recitals F and G above, (ii) Cytovance agrees to deliver the products as described in the Change Orders in accordance with the delivery dates and subject to the terms of this Agreement, (iii) subject to the terms and conditions of this Agreement, and provided that all raw materials are available as targeted and there are no supply chain disruptions, delays attributable to GTBP, or other delays outside of Cytovance's control, Cytovance agrees that for each week that Cytovance has not delivered products, components and/or materials as required by the delivery schedules set forth in the Change Orders, GTBP shall have the right, at its election, to increase by five percent (5%), up to a maximum of forty percent (40%), the portion of the outstanding balance under Subsequent SOW Invoices that GTBP shall pay through the issuance of GTBP Common Stock and (iv) Cytovance and GTBP agree to enter into this Agreement to effectuate the agreed upon payment terms, as described above.

I. Accordingly, at the Initial Closing, (i) the parties desire to execute and deliver the Change Orders, and (ii) Cytovance desires to purchase from GTBP, and GTBP desires to issue and sell to Cytovance, the Initial Shares in exchange for the Initial In-Kind Payment, on the terms and conditions set forth herein.

J. At the Milestone Closings, Cytovance desires to purchase from GTBP, and GTBP desires to issue and sell to Cytovance, the Milestone Shares in exchange for the Milestone In-Kind Payments, on the terms and conditions set forth herein.

AGREEMENTS

In consideration of the foregoing recitals, which are hereby incorporated into this Agreement and made a part hereof, and the mutual promises, representations, warranties, and covenants hereinafter set forth, and for other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, the parties hereto agree as follows:

1. AGREEMENT TO SELL AND PURCHASE.

1.1 Sale of Initial Shares. Subject to the terms and conditions hereof, (a) at the Initial Closing, GTBP hereby agrees to issue and sell to Cytovance, and Cytovance agrees to purchase from GTBP, such number of shares of GTBP Common Stock which is equal to the quotient (rounded down to the nearest whole share) determined by dividing (a) the Initial In-Kind Payment by (b) the Per Share Purchase Price (the "Initial Shares"), in each case free and clear of all Liens

other than Permitted Liens. The purchase price for the Initial Shares being purchased by Cytovance will be paid at the Initial Closing in the form of the Initial In-Kind Payment. The purchase and sale of the Initial Shares shall take place at a closing (the "Initial Closing") to be held in accordance with Section 2 hereof.

1.2 Sale of Milestone GTBP Shares. Subject to the terms and conditions hereof, at each Milestone Closing, GTBP hereby agrees to issue and sell to Cytovance, and Cytovance agrees to purchase from GTBP, at the Per Share Purchase Price, such number of shares of GTBP Common Stock which is equal to the quotient (rounded down to the nearest whole share) determined by dividing (a) the applicable Milestone In-Kind Payment, by (b) the Per Share Purchase Price (the "Milestone Shares" and, together with the Initial Shares, the "Shares"), in each case free and clear of all Liens other than Permitted Liens. The purchase price for the Milestone Shares being purchased by Cytovance will be paid at the respective Milestone Closings in the form of the Milestone In-Kind Payments. Each purchase and sale of the Milestone Shares shall take place at a closing (each, a "Milestone Closing" and, collectively, the "Milestone Closings") to be held in accordance with Section 3 hereof.

2. INITIAL CLOSING; DELIVERIES AND PAYMENTS.

2.1 Initial Closing. Subject to satisfaction or waiver of the terms and conditions contained herein, the Initial Closing shall take place remotely via the exchange of documents and signatures on the date hereof or at such other time or place as Cytovance and GTBP may mutually agree (such date is hereinafter referred to as the "Initial Closing Date").

2.2 Deliveries by GTBP at the Initial Closing. Subject to the terms and conditions of this Agreement, GTBP shall, in connection with the Initial Closing:

(a) Deliver to Cytovance at the Initial Closing a compliance certificate, executed by a duly authorized officer of GTBP, dated the date of the Initial Closing, to the effect that the conditions specified in Section 7.1 to be satisfied by GTBP at or prior to the Initial Closing have been satisfied;

(b) Deliver to Cytovance at the Initial Closing an instruction letter from GTBP provided to its stock transfer agent instructing such stock transfer agent to issue to Cytovance the Initial Shares in book entry form;

(c) Deliver to Cytovance at the Initial Closing a Cross Receipt and Acknowledgement, executed by a duly authorized officer of GTBP and substantially in the form attached hereto as Exhibit A;

(d) Pay to Cytovance $3,251,267.75, being fifty (50%) of the Outstanding Balance under the Outstanding Invoices, in cash by wire transfer of immediately available funds to the account(s) designated by Cytovance as follows: $1,251,267.75 on September 1, 2022; $1,000,000.00 on October 3, 2022; and $1,000,000.00 on November 1, 2022; and

(e) Deliver to Cytovance the two Change Orders attached hereto as Exhibit C, executed by a duly authorized officer of GTBP.

2.3 Deliveries by Cytovance at the Initial Closing. Subject to the terms and conditions of this Agreement, Cytovance shall deliver the following to GTBP at the Initial Closing:

(a) A compliance certificate, executed by a duly authorized officer of Cytovance, dated the date of the Initial Closing, to the effect that the conditions specified in Section 7.2 to be satisfied by Cytovance at or prior to the Initial Closing have been satisfied;

(b) A Cross Receipt and Acknowledgement, executed by a duly authorized officer of the Cytovance and substantially in the form attached hereto as Exhibit A; and

(c) The two Change Orders attached hereto as Exhibit C, executed by a duly authorized officer of Cytovance.

3. MILESTONE CLOSINGS.

3.1 Milestone Closings. Subject to satisfaction or waiver of the terms and conditions contained herein, the Milestone Closings shall take place remotely via the exchange of documents and signatures on the payment due date set forth in each Subsequent SOW Invoice or at such other time or place as Cytovance and GTBP may mutually agree (each such date is hereinafter referred to as a "Milestone Closing Date").

3.2 Deliveries by GTBP at each Milestone Closing. Subject to the terms and conditions of this Agreement, GTBP shall deliver the following to Cytovance at each Milestone Closing:

(a) A compliance certificate, executed by a duly authorized officer of GTBP, dated the date of such Milestone Closing, to the effect that the conditions specified in Section 7.1 to be satisfied by GTBP at or prior to such Milestone Closing have been satisfied;

(b) An instruction letter from GTBP provided to its stock transfer agent instructing such stock transfer agent to issue to Cytovance the Milestone Shares in book entry form at such Milestone Closing;

(c) A Cross Receipt and Acknowledgement, executed by a duly authorized officer of GTBP and substantially in the form attached hereto as Exhibit B; and

(d) Fifty percent (50%) of the outstanding balance of the Subsequent SOW Invoice giving rise to such Milestone Closing, in cash by wire transfer of immediately available funds to the account(s) designated by Cytovance.

3.3 Deliveries by Cytovance at each Milestone Closing. Subject to the terms and conditions of this Agreement, Cytovance shall deliver the following to GTBP at each Milestone Closing:

(a) A compliance certificate, executed by a duly authorized officer of Cytovance, dated the date of such Milestone Closing, to the effect that the conditions specified in Section 7.2 to be satisfied by Cytovance at or prior to such Milestone Closing have been satisfied; and

(b) A Cross Receipt and Acknowledgement, executed by a duly authorized officer of Cytovance and in substantially the form attached hereto as Exhibit B.

4. BENEFICIAL OWNERSHIP LIMITATION. Notwithstanding anything herein to the contrary, the number of shares of GTBP Common Stock issued to Cytovance pursuant to this Agreement shall not exceed the number of shares of GTBP Common Stock that, when aggregated with all other shares of GTBP Common Stock then beneficially owned by Cytovance, would result in Cytovance beneficially owning more than four and 90/100 precent (4.90%) of the total number of issued and outstanding shares of GTBP Common Stock, as determined in accordance with Section 13 of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), and Rule 13d-3 promulgated thereunder (the "Beneficial Ownership Limitation"). In the event any of the Shares issuable to Cytovance at any Closing would exceed the Beneficial Ownership Limitation (the "Excess Shares"), GTBP shall issue such Excess Shares to Cytovance in quarterly installments on the last day of each calendar quarter, but in any event not in excess of the Beneficial Ownership Limitation as determined at such time, until all of such Excess Shares have been issued in accordance with this Agreement. Prior to the issuance of any Excess Shares pursuant to this Section 4, GTBP shall give written notice to Cytovance at least ten (10) days prior to the end of the applicable calendar quarter setting forth (a) the number of Excess Shares to be issued to Cytovance at the end of such calendar quarter (which shall not exceed the number of Excess Shares that GTBP is then obligated to issue) and (b) the percentage of the total number of issued and outstanding shares of GTBP Common Stock that Cytovance will own after giving effect to such issuance. GTBP shall not issue more Excess Shares for any quarter than the number of Excess Shares set forth in such notice delivered by GTBP for such quarter. If GTBP fails to provide such notice for any calendar quarter, then, without limiting the rights and obligations of the parties under this Section 4, no Excess Shares shall be issued to Cytovance until the next calendar quarter in which GTBP delivers a notice as provided in this Section.

5. REPRESENTATIONS AND WARRANTIES OF GTBP. GTBP hereby represents and warrants to Cytovance that the representations and warranties set forth in this Section 5 are true and correct as of the Signing Date and as of each Closing Date (provided, that the accuracy of any representation or warranty that by its terms speaks only as of a specified date shall be determined solely as of such date).

5.1 Organization. GTBP is a corporation duly organized, validly existing and in good standing under the laws of the State of Delaware. GTBP has all necessary power and authority to carry on its business as now conducted and to own and lease the properties and assets it now owns and leases.

5.2 Authorization of Agreement; No Conflict.

(a) GTBP has all requisite power and authority to execute and deliver this Agreement and the other agreements to be executed and delivered by GTBP pursuant to this Agreement and to consummate the transactions provided for herein and therein. The execution and delivery by GTBP of this Agreement and the other agreements to be executed and delivered by GTBP pursuant to this Agreement and the performance by GTBP of the obligations to be performed hereunder and thereunder have been duly authorized by GTBP by all requisite action. This Agreement is, and each other agreement and document to be executed by GTBP pursuant

hereto will be when so executed, a valid and binding obligation of GTBP, enforceable in accordance with its terms, except that enforcement may be limited by bankruptcy, insolvency, reorganization, moratorium or other similar laws affecting creditors rights generally and by general equitable principles.

(b) The execution and delivery of this Agreement and the other agreements to be executed and delivered pursuant to this Agreement and the consummation of the transactions contemplated hereby and thereby do not and will not, with or without the giving of notice or the passage of time, conflict with, result in or constitute a breach, default, right to accelerate or loss of rights under, or result in the creation of any Lien pursuant to, the terms or conditions of GTBP's Organizational Documents, any law or any mortgage, lease, franchise, license, permit, contract, agreement and/or instrument to which GTBP is a party or by which GTBP is bound.

5.3 Valid Issuance of Shares. The Shares, when issued and delivered in accordance with the terms hereof, will be duly authorized, validly issued, fully paid and non-assessable and no personal liability will attach to the ownership thereof and will be free and clear of all Liens other than Permitted Liens. The issuance of the Shares in accordance with the terms of this Agreement will comply in all material respects with all applicable laws, including all federal, state and foreign securities laws. The issuance of the Shares will not, at the time of issuance in accordance with the terms of this Agreement, violate any pre-emptive rights, rights of first offer, rights of first refusal or similar rights of any Person.

5.4 GTBP SEC Documents. All statements, reports, schedules, forms and other documents (including exhibits and all information incorporated by reference) required to have been filed by GTBP with the Securities and Exchange Commission (the "SEC") since July 1, 2021 (the "GTBP SEC Documents") have been so filed on a timely basis. A true and complete copy of each GTBP SEC Document is available on the website maintained by the SEC at http://www.sec.gov. As of their respective filing dates (or, if amended or superseded by a filing prior to the Signing Date, then on the date of such later filing), each of the GTBP SEC Documents complied in all material respects with the requirements of the Securities Act of 1933, as amended (the "Securities Act"), and the Exchange Act, as the case may be, and the rules and regulations of the SEC promulgated thereunder applicable to such GTBP SEC Documents. None of the GTBP SEC Documents, as of their respective filing dates, contained any untrue statement of a material fact or omitted to state a material fact required to be stated therein or necessary to make the statements therein not misleading, except to the extent corrected by a subsequently filed GTBP SEC Document.

5.5 Financial Statements. The consolidated financial statements of GTBP, including the notes thereto, included in the GTBP SEC Documents complied as to form in all material respects with the published rules and regulations of the SEC with respect thereto as of their respective dates, were prepared in accordance with U.S. generally accepted accounting principles ("GAAP") applied on a consistent basis throughout the periods indicated (except as may be indicated in the notes thereto, except in the case of pro forma statements, or, in the case of unaudited financial statements, except as permitted under Form 10-Q or Form 8-K or any successor thereto, under the Exchange Act) and fairly presented in all material respects the consolidated financial position of GTBP and its consolidated Subsidiaries as of the respective dates thereof and the consolidated results of GTBP's operations and cash flows for the periods indicated (except that

unaudited financial statements may not include all the footnotes required by GAAP for audited financials and were or are subject to normal and recurring year-end adjustments that are not material, individually or in the aggregate).

5.6 No Undisclosed Liabilities. Neither GTBP nor any of its Subsidiaries has any material liabilities, whether accrued, absolute, contingent, unliquidated or otherwise, whether due or to become due, known or unknown, regardless of when asserted, except liabilities or obligations: (a) stated or adequately reserved against in the most recent balance sheet contained in the GTBP SEC Documents; (b) incurred in the ordinary course of business consistent with past practice since the date of the most recent balance sheet contained in the GTBP SEC Documents; or (c) that are not required to be disclosed or reflected on financial statements prepared in accordance with GAAP.

5.7 Rule 144 Status. GTBP(i) is subject to the reporting requirements of Section 13 or 15(d) of the Exchange Act, (ii) has filed "Form 10" information more than one year prior to the date of this Agreement as provided in Rule 144(i)(2) promulgated under the Securities Act, and (iii) has filed all periodic reports required to be filed by Section 13 or 15(d) of the Exchange Act, as applicable, during the 12 months preceding the date of this Agreement.

5.8 Litigation. There is no Proceeding pending or, to GTBP's knowledge, threatened against GTBP which will adversely affect or restrict GTBP's ability to consummate the transactions contemplated by this Agreement.

5.9 Broker's Fees. No broker, finder or investment banker is entitled to any brokerage, finder's or other fee or commission in connection with the transactions contemplated herein based upon arrangements made by or on behalf of GTBP.

6. REPRESENTATIONS AND WARRANTIES OF CYTOVANCE. Cytovance hereby represents and warrants to GTBP that the representations and warranties set forth in this Section 6 are true and correct as of the Signing Date and as of each Closing Date (provided, that the accuracy of any representation or warranty that by its terms speaks only as of a specified date shall be determined solely as of such date).

6.1 Organization. Cytovance is a corporation duly organized, validly existing and in good standing under the laws of the State of Delaware. Cytovance has all necessary power and authority to carry on its business as now conducted and to own and lease the properties and assets it now owns and leases.

6.2 Authorization of Agreement; No Conflict.

(a) Cytovance has all requisite power and authority to execute and deliver this Agreement and the other agreements to be executed and delivered by Cytovance pursuant to this Agreement and to consummate the transactions provided for herein and therein. The execution and delivery by Cytovance of this Agreement and the other agreements to be executed and delivered by Cytovance pursuant to this Agreement and the performance by Cytovance of the obligations to be performed hereunder and thereunder have been duly authorized by Cytovance by all requisite action. This Agreement is, and each other agreement and document to be executed by Cytovance pursuant hereto will be when so executed, a valid and binding obligation of Cytovance,

enforceable in accordance with its terms, except that enforcement may be limited by bankruptcy, insolvency, reorganization, moratorium or other similar laws affecting creditors rights generally and by general equitable principles.

(b) The execution and delivery of this Agreement and the other agreements to be executed and delivered pursuant to this Agreement and the consummation of the transactions contemplated hereby and thereby do not and will not, with or without the giving of notice or the passage of time, conflict with, result in or constitute a breach, default, right to accelerate or loss of rights under, or result in the creation of any Lien pursuant to, the terms or conditions of Cytovance's Organizational Documents, any law or any mortgage, lease, franchise, license, permit, contract, agreement and/or instrument to which Cytovance is a party or by which Cytovance is bound.

6.3 Investment Representations.

(a) Cytovance is an accredited investor as defined in Rule 501(a) of Regulation D promulgated under the Securities Act.Cytovance understands that the Shares will not be registered under the Securities Act on the date of issuance, and the registration of the Shares will occur after the issuance of the Shares pursuant to the filing and effectiveness of the Registration Statement(s). The issuance of the Shares will be made by reason of a specific exemption from the registration provisions of the Securities Act which depends upon, among other things, the accuracy of Cytovance's representations as expressed herein.Cytovance understands that the Shares are "restricted securities" under Rule 144 promulgated under the Securities Act and that, pursuant to the Securities Act and applicable state securities laws, Cytovance must hold the Shares indefinitely unless they are registered in accordance with the Registration Statement or are otherwise eligible for resale pursuant the requirements of the Securities Act and the regulations promulgated thereunder.Cytovance further acknowledges that if an exemption from registration or qualification is available, it may be conditioned on various requirements of Rule 144 which are outside of Cytovance's control, and which GTBP may not be able to satisfy.Litigation. There is no Proceeding pending or, to Cytovance's knowledge, threatened against Cytovance which will adversely affect or restrict Cytovance's ability to consummate the transactions contemplated by this Agreement.

6.5 Broker's Fees. No broker, finder or investment banker is entitled to any brokerage, finder's or other fee or commission in connection with the transactions contemplated herein based upon arrangements made by or on behalf of Cytovance.

7. CONDITIONS TO CLOSING.

7.1 Conditions to Cytovance's Obligations at the Initial Closing and the Milestone Closings. Cytovance's obligations to purchase the Shares at the Initial Closing and the Milestone Closings are subject to the satisfaction, at or prior to the applicable Closing Date, of the following conditions:

(a) Representations and Warranties True; Performance of Obligations. The representations and warranties in Section 5 made by GTBP shall be true and correct in all material respects on and as of the applicable Closing Date with the same force and effect as if they had been

made on and as of such Closing Date, and GTBP shall have performed and complied in all material respects with all agreements and conditions herein required to be performed or complied with by GTBP on or before the applicable Closing Date.

(b) Consents, Permits, and Waivers. GTBP shall have obtained or submitted any and all consents, approvals, waivers, qualifications, permits, orders or authorizations of, filings with, or notices to the board of directors of GTBP, the stockholders of GTBP and any governmental authority or any other third party, including without limitation, the qualification of the Shares, or the satisfaction of registration exemptions, under applicable state securities or blue sky laws, in each case, required in connection with (i) GTBP's valid execution, delivery and performance of this Agreement, (ii) the offer, sale and issuance of the Shares, and (iii) the consummation of any other transaction contemplated on the part of GTBP in connection with this Agreement.

(c) Deliveries. GTBP shall have delivered to Cytovance the items required to be delivered by GTBP pursuant to Section 2.2 or Section 3.2, as applicable.

(d) Legal Investment. At the time of the applicable Closing, the sale of the Shares to, and purchase of the Shares by, Cytovance hereunder shall be legally permitted by all laws and regulations to which Cytovance and GTBP are subject.

Notwithstanding anything herein to the contrary, if any of the conditions set forth in this Section 7.1 are not satisfied (or waived by Cytovance) as of the applicable Milestone Closing Date, GTBP shall pay one hundred percent (100%) of the outstanding balance of the corresponding Subsequent SOW Invoice(s) in cash on the payment due date set forth in such Subsequent SOW Invoice(s).

7.2 Conditions to GTBP's Obligations at the Initial Closing and the Milestone Closings. GTBP's obligations to issue and sell the Shares at the Initial Closing and the Milestone Closings are subject to the satisfaction, at or prior to the applicable Closing Date, of the following conditions:

(a) Representations and Warranties True; Performance of Obligations. The representations and warranties in Section 6 made by Cytovance shall be true and correct in all material respects on and as of the applicable Closing Date with the same force and effect as if they had been made on and as of such Closing Date, and Cytovance shall have performed and complied in all material respects with all agreements and conditions herein required to be performed or complied with by Cytovance on or before the applicable Closing Date.

(b) Consents, Permits, and Waivers. Cytovance shall have obtained or submitted any and all consents, approvals, waivers, qualifications, permits, orders or authorizations of, filings with, or notices to the board of directors of Cytovance, the stockholders of Cytovance and any governmental authority or any other third party, required in connection with (i) Cytovance's valid execution, delivery and performance of this Agreement, (ii) the purchase of the Shares, and (iii) the consummation of any other transaction contemplated on the part of Cytovance in connection with this Agreement.

(c) Deliveries. Cytovance shall have delivered to GTBP the items required to be delivered by Cytovance pursuant to Section 2.3 or Section 3.3, as applicable.

(d) Legal Investment. At the time of the applicable Closing, the sale of the Shares to, and purchase of the Shares by, Cytovance hereunder shall be legally permitted by all laws and regulations to which Cytovance and GTBP are subject.

Notwithstanding anything herein to the contrary, if any of the conditions set forth in this Section 7.2 are not satisfied (or waived by GTBP) as of the applicable Milestone Closing Date, GTBP shall pay one hundred percent (100%) of the outstanding balance of the corresponding Subsequent SOW Invoice(s), subject to the terms of this Agreement, in payment of Common Stock of GTBP.

8. COVENANTS OF THE PARTIES.

8.1 Further Assurances. Each party hereto agrees that, from time to time after each Closing Date, it will execute and deliver, or cause its Affiliates to execute and deliver, such further instruments, and take (or cause its Affiliates to take) such other action, as may be reasonably necessary to carry out the purposes and intents of this Agreement, including cooperating with the other party hereto, to the extent reasonably requested by such other party and at such other party's sole expense, to enforce rights and obligations provided herein against any third party.

8.2 Compliance with Rule 144.

(a) With a view to making available to Cytovance the benefits of Rule 144 promulgated under the Securities Act, as such rule may be amended from time to time ("Rule 144"), and other rules and regulations of the SEC that may at any time permit Cytovance to sell shares of GTBP Common Stock without registration, until Cytovance would be permitted to resell all shares of GTBP Common Stock that have been or will be issued to Cytovance pursuant to this Agreement pursuant to the last sentence of Rule 144(b)(1)(i), GTBP covenants that it will (i) file in a timely manner all reports and other documents required, if any, to be filed by it under the Securities Act and the Exchange Act and the rules and regulations adopted thereunder and (ii) make available information necessary to comply with Rule 144, if available with respect to resales of such shares of GTBP Common Stock under Rule 144, at all times, all to the extent required from time to time to enable Cytovance to sell such shares of GTBP Common Stock without registration under the Securities Act within the limitation of the exemptions provided by Rule 144. Upon the written request of Cytovance, GTBP will deliver to Cytovance a written statement as to GTBP's compliance with such requirements. GTBP shall, at its sole cost, take such action as reasonably necessary to cooperate in any sale of any such shares of GTBP Common Stock by Cytovance in accordance with Rule 144, including arranging for any instructions or legal opinions in an appropriate form under Rule 144 to GTBP's stock transfer agent.

(b) Upon the written request of Cytovance, any restrictive legend set forth on a certificate or book-entry notation representing Cytovance's shares of GTBP Common Stock shall be removed and GTBP shall issue a certificate or book-entry notation without such restrictive legend if such shares are eligible for sale without restriction under Rule 144(b)(1).

(c) Cytovance shall limit its daily resale of any shares eligible for resale pursuant to Rule 144 to the lesser of (i) fifty thousand (50,000) shares or (ii) one-third (1/3) of the

average daily trading volume for the week preceding the proposed sale. This covenant shall terminate if GTBP breaches any provision of this Section.

9. MUTUAL RELEASE.

9.1 Release of Claims. Subject to the representations and warranties under this Agreement being and remaining true in all respects, and subject to the performance of and compliance with all obligations under this Agreement, each of the Parties (a "Releasing Party"), on behalf of itself, its predecessors, successors and assigns, its agents, employees or representatives, and all persons acting by, through, under or in concert with it, and each of them, hereby releases and forever discharges the other party together with its predecessors, successors, direct and indirect parent companies, direct and indirect subsidiary companies, companies under common control with any of the foregoing, affiliates, and assigns, and its and their past, present, and future officers, directors, shareholders, interest holders, members, partners, attorneys, agents, employees, managers, representatives, assigns, and successors in interest, and all persons acting by, through, under or in concert with them, and each of them (a "Released Party"), from all known and unknown charges, complaints, claims, grievances, liabilities, obligations, promises, agreements, controversies, damages, actions, causes of action, suits, rights, demands, costs, losses, debts, penalties, fees, expenses (including attorneys' fees and costs actually incurred) and punitive damages, of any nature whatsoever, whether at law or in equity, or known or unknown, which such Releasing Party has, or may have had, against a Released Party, whether or not apparent or yet to be discovered, or which may hereafter develop, for any acts or omissions arising prior to the effectiveness of this Agreement, including any and all claims relating to or arising out of any obligation under the MSA, any agreement between the Parties, any other matter between the Parties, and/or any claims under federal, state, or local law, rule, or regulation. Notwithstanding the foregoing, nothing in this Section 9.1 will constitute a release or waiver of any rights a Releasing Party may have against any Released Party under this Agreement or the documents delivered pursuant hereto.

9.2 Unknown Claims Each party understands that the laws of many states, including Section 1542 of the California Civil Code, provide substantially the following: A GENERAL RELEASE DOES NOT EXTEND TO CLAIMS THAT THE CREDITOR OR RELEASING PARTY DOES NOT KNOW OR SUSPECT TO EXIST IN HIS OR HER FAVOR AT THE TIME OF EXECUTING THE RELEASE AND THAT, IF KNOWN BY HIM OR HER, WOULD HAVE MATERIALLY AFFECTED HIS OR HER SETTLEMENT WITH THE DEBTOR OR RELEASED PARTY. Each party agrees and acknowledges that the released claims extend to and include unknown and unsuspected claims. Each party has made an investigation of the facts pertaining to this Agreement and to the released claims as it deems necessary. Each party is aware that it may hereafter discover facts in addition to, contrary to, or different from those it now knows or believes to be true with respect to the matters set forth herein. Nevertheless, it is the intention of the parties to fully, finally, and forever settle and release all claims of any kind or nature whatsoever to the extent set forth in Section 9.1. In furtherance of the parties' intent, unless terminated in accordance with Section 9.3, the release in this Agreement shall remain in full and complete effect notwithstanding the discovery or existence of any additional, contrary, or different facts.

9.3 Termination of Release. The release set forth in Section 9.1 shall automatically terminate as to the Releasing Party in the event that any representation or warranty provided by the other party under this Agreement is untrue in any material respect, or the other party fails to comply with its covenants and all of its other obligations under this Agreement in any material respect or any obligation provided in the MSA or the SOWs, as modified by the Change Orders.

10. TERMINATION.

10.1 Termination. With respect to each SOW, this Agreement shall automatically terminate concurrently with the expiration thereof upon the completion of services thereunder or termination of such SOW in accordance with its terms and/or the terms of the MSA; provided, however, that the terms of this Agreement shall continue to apply to the payment and satisfaction of, and deliverables under, any SOW that remains outstanding.

10.2 Effect of Termination. In addition to the provisions of Section 4.2(g) and Section 20 of the MSA, if any Raw Materials (as defined in the MSA) remain after the termination of an SOW in accordance with its terms and/or the terms of the MSA, GTBP may elect, at its expense, to have Cytovance ship the Raw Materials to GTBP or its designee; provided, that GTBP purchases (or has previously purchased) such Raw Materials from Cytovance at the cost value thereof prior to shipment.

11. MISCELLANEOUS.

11.1 Governing Law; Waiver of Jury Trial. This Agreement shall be governed by the laws of the State of Delaware and the federal laws of the United States without giving effect to any rule or provision thereof which would cause the application of the law of any other state. EACH OF THE PARTIES HEREBY IRREVOCABLY WAIVES ANY AND ALL RIGHT TO TRIAL BY JURY IN ANY PROCEEDING ARISING OUT OF OR RELATING TO THIS AGREEMENT. The parties (a) hereby irrevocably and unconditionally submit to the jurisdiction of the state and federal courts located in Delaware, for the purpose of any suit, action or other proceeding arising out of or based upon this Agreement, (b) agree not to commence any suit, action or other proceeding arising out of or based upon this Agreement except in a state or federal court located in Delaware, and (c) hereby waive, and agree not to assert, by way of motion, as a defense, or otherwise, in any such suit, action or proceeding, any claim that it is not subject personally to the jurisdiction of the above-named courts, that its property is exempt or immune from attachment or execution, that the suit, action or proceeding is brought in an inconvenient forum, that the venue of the suit, action or proceeding is improper or that this Agreement or the subject matter hereof may not be enforced in or by such courts.

11.2 Survival. The representations and warranties of each party made herein shall survive any investigation made by the other party, any Closing and any termination of this Agreement until thirty (30) days following the expiration of the applicable statute of limitations (giving effect to any extensions and waivers thereof). All statements as to factual matters contained in any certificate or other instrument delivered by or on behalf of a party pursuant hereto in connection with the transactions contemplated hereby shall be deemed to be representations and warranties by such party hereunder solely as of the date of such certificate or instrument. Sections

8.1, 8.2, 9, unless terminated in accordance with Section 9.3, and 11 shall survive the termination of this Agreement.

11.3 Successors and Assigns. Except as otherwise expressly provided herein, the provisions hereof shall inure to the benefit of, and be binding upon, the successors, assigns, heirs, executors and administrators of the parties hereto; provided, that no party may assign, delegate or otherwise transfer any of its rights or obligations under this Agreement without the consent of each other party hereto, except that Cytovance may assign its rights hereunder to its Affiliates.

11.4 Entire Agreement; Conflict. This Agreement, the Exhibits and Schedules hereto, the Change Orders, and the other documents delivered pursuant hereto constitute the full and entire understanding and agreement between the parties with regard to the subjects hereof and no party shall be liable or bound to any other in any manner by any representations, warranties, covenants and agreements except as specifically set forth herein and therein. The MSA shall remain in effect in accordance with its terms except as amended by the terms of this Agreement and the Change Orders. If there is a conflict between the terms of this Agreement and the terms and conditions of the MSA, any SOWs, or any Change Orders, the terms and conditions of this Agreement shall control.

11.5 Severability. In case any provision of the Agreement shall be invalid, illegal or unenforceable, the validity, legality and enforceability of the remaining provisions shall not in any way be affected or impaired thereby.

11.6 Amendment and Waiver.

(a) This Agreement may be amended or modified only upon the written consent of Cytovance and GTBP.

(b) The obligations of GTBP and the rights of the holders of the Shares under this Agreement may be waived only with the written consent of Cytovance. The obligations of Cytovance and the rights of GTBP under this Agreement may be waived only with the written consent of GTBP.

11.7 Delays or Omissions. It is agreed that no delay or omission to exercise any right, power or remedy accruing to any party, upon any breach, default or noncompliance by another party under this Agreement shall impair any such right, power or remedy, nor shall it be construed to be a waiver of any such breach, default or noncompliance, or any acquiescence therein, or of or in any similar breach, default or noncompliance thereafter occurring. It is further agreed that any waiver, permit, consent or approval of any kind or character on any party's part of any breach, default or noncompliance under this Agreement or any waiver on such party's part of any provisions or conditions of this Agreement must be in writing and shall be effective only to the extent specifically set forth in such writing. All remedies, either under this Agreement, by law, or otherwise afforded to any party, shall be cumulative and not alternative.

11.8 Notices. All notices required or permitted hereunder shall be in writing and shall be deemed effectively given: (a) upon personal delivery to the party to be notified, (b) when sent by confirmed electronic mail if sent during normal business hours of the recipient, if not, then on the next business day, or if sent by facsimile, at the time that receipt thereof has been acknowledged

by electronic confirmation or otherwise, (c) five (5) days after having been sent by registered or certified mail, return receipt requested, postage prepaid, or (d) one (1) day after deposit with a nationally recognized overnight courier, specifying next day delivery, with written verification of receipt. All communications shall be sent to the parties at their addresses set forth on the signature page hereto or at such other address as Cytovance or GTBP may designate by five (5) days' advance written notice to the other party.

11.9 Expenses. Each of Cytovance and GTBP will bear all of its own expenses in connection with the preparation, execution and negotiation of this Agreement and the transactions contemplated hereby and thereby.

11.10 Attorneys' Fees. In the event that any dispute between the parties to this Agreement should result in litigation, the prevailing party in such dispute shall be entitled to recover from the losing party all fees, costs and expenses of enforcing any right of such prevailing party under or with respect to this Agreement or any other document delivered pursuant hereto, including without limitation, such reasonable fees and expenses of attorneys and accountants, which shall include, without limitation, all fees, costs and expenses of appeals.

11.11 Construction. In this Agreement (except where the context otherwise requires): (a) any reference to a Recital, Section, Exhibit or Schedule is to the relevant Recital, Section, Exhibit or Schedule of or to this Agreement and any reference to a subsection or clause is to the relevant subsection or clause of the Section, Exhibit or Schedule in which it appears; (b) the Section headings are included for convenience only and shall not modify or affect the construction or interpretation of this Agreement; (c) references to "Dollars" or "$" shall mean United States Dollars unless otherwise specifically noted; (d) the term "including" shall be deemed to be immediately followed by the term "but not limited to"; (e) the words "hereof," "herein" and "hereunder" and words of similar import shall be deemed to refer to this Agreement as a whole and not any particular provision of this Agreement; (f) references to a "party" or "parties" shall mean Cytovance or GTBP, or both of them, as the context requires; (g) terms defined in the singular shall have a comparable meaning when used in the plural and vice versa; (h) references to statutes and related regulations shall include all amendments of the same and any successor or replacement statutes and regulations; (i) references to any Person shall be deemed to mean and include the predecessors, successors and permitted assigns of such Person (or, in the case of a governmental authority, Persons succeeding to the relevant functions of such Person); and (j) the language used in this Agreement shall be deemed to be the language chosen by the parties hereto to express their mutual intent, and if an ambiguity or question of intent or interpretation arises, this Agreement will be construed as if drafted jointly by the parties hereto and no presumption or burden of proof will arise favoring or disfavoring any Person by virtue of the authorship of any of the provisions of this Agreement.

11.12 Counterparts. This Agreement may be delivered by facsimile or other electronic means (i.e., PDF) of original signatures and may be executed in counterparts, each of which shall be considered one and the same agreement and shall become effective when such counterparts have been signed by each party and delivered to the other parties.

[Signature page follows.]

IN WITNESS WHEREOF, the parties hereto have executed this Settlement and Investment Agreement as of the Signing Date.

CYTOVANCE:

CYTOVANCE BIOLOGICS, INC.

By: DocuSigned by: David knauss
Name: David Knauss
Title: Chief Financial Officer

Address:
Cytovance Biologics, Inc.
800 Research Parkway, Suite 200
Oklahoma City, OK 73104
Attention: David Knauss
Email: knaussd@splpharma.com

GTBP:

GT BIOPHARMA, INC.

By: DocuSigned by: Michael Breen
Name: Michael Breen
Title: Executive Chairman of the Board and Interim Chief Executive Officer

Address:
GT Biopharma, Inc.
8000 Marina Blvd., Suite 100
Brisbane, CA 94005
Attention: Chief Executive Officer
Email: mb@gtbiopharma.com

EXHIBIT A

INITIAL CLOSING
CROSS RECEIPT AND ACKNOWLEDGEMENT

[Omitted]

EXHIBIT B

MILESTONE CLOSING
CROSS RECEIPT AND ACKNOWLEDGEMENT

[Omitted]

EXHIBIT C

CHANGE ORDERS

[Omitted]

EXHIBIT D

OUTSTANDING INVOICES

[Omitted]

SCHEDULE 1

DEFINITIONS

Certain Definitions. Except as otherwise defined in this Agreement or as the context may otherwise require, the following terms shall have the respective meanings set forth below whenever used in this Agreement:

"Affiliate" means, with respect to any specified Person, any other Person that, directly or indirectly through one or more intermediaries, controls, is controlled by or is under common control with, such specified Person. For purposes hereof, the term "control," or any variation thereof, means the possession, directly or indirectly, of the power to direct or cause the direction of the management and policies of a Person, whether through the ownership of voting securities, by contract or otherwise. For the avoidance of doubt, any partner, officer, director, manager or employee of such Person shall be deemed Affiliates for the purposes of this Agreement.

"Agreement" has the meaning set forth in the preamble of this Agreement.

"Beneficial Ownership Limitation" has the meaning set forth in Section 4.

"Change Orders" means an agreed-upon amendment, change, or revision to an applicable SOW, including the two Change Orders identified in Exhibit C.

"Closing" and "Closings" mean, individually or collectively, as the context requires, the Initial Closing and any Milestone Closing.

"Closing Date" means, with respect to the Initial Closing, the Initial Closing Date, and with respect to any Milestone Closing, the Milestone Closing Date.

"Cytovance" has the meaning set forth in the preamble of this Agreement.

"Excess Shares" has the meaning set forth in Section 4.

"Exchange Act" has the meaning set forth in Section 4.

"GAAP" has the meaning set forth in Section 5.5.

"GTBP" has the meaning set forth in the preamble of this Agreement.

"GTBP Common Stock" means the common stock, par value $0.001 per share, of GTBP.

"GTBP SEC Documents" has the meaning set forth in Section 5.4.

"Initial Closing" has the meaning set forth in Section 1.1.

"Initial Closing Date" has the meaning set forth in Section 2.1.

"Initial Shares" has the meaning set forth in Section 1.1.

"Initial In-Kind Payment" means Cytovance's agreement and acknowledgment that fifty percent (50%) of the Outstanding Balance under the Outstanding Invoices has been fully satisfied and paid in full through the issuance of the Initial Shares hereunder.

"Lien" means (a) any interest in property (whether real, personal or mixed and whether tangible or intangible) which secures an obligation owed to, or a claim by, a Person other than the owner of such property, whether such interest is based on the common law, statute or contract, including, without limitation, any such interest arising from a lease, mortgage, charge, pledge, security agreement, conditional sale, trust receipt or deposit in trust, or arising from a consignment of bailment given for security purposes (other than a trust receipt or deposit given in the ordinary course of business which does not secure any obligation for borrowed money), (b) any encumbrance upon such property which does not secure such an obligation, and (c) any exception to or defect in the title to or ownership interest in such property, including, without limitation, reservations, rights of entry, possibilities of reverter, encroachments, easements, rights of way, restrictive covenants and licenses.

"Milestone Closing" has the meaning set forth in Section 1.2.

"Milestone Closing Date" has the meaning set forth in Section 3.1.

"Milestone In-Kind Payment" means, with respect to each Subsequent SOW Invoice, Cytovance's agreement and acknowledgment that fifty percent (50%) of the outstanding balance of such Subsequent SOW Invoice has been fully satisfied and paid in full through the issuance of the Milestone Shares hereunder.

"Milestone Shares" has the meaning set forth in Section 1.2.

"MSA" has the meaning set forth in Recital A.

"Organizational Documents" means: (a) the articles or certificate of incorporation and the bylaws of a corporation; (b) the partnership agreement and any statement of partnership of a general partnership; (c) the limited partnership agreement and the certificate or articles of limited partnership of a limited partnership; (d) the limited liability partnership agreement and the certificate or articles of limited liability partnership of a limited liability partnership; (e) the operating agreement or limited liability company agreement and the articles of organization or certificate of formation of a limited liability company; (f) any charter or similar document adopted or filed in connection with the creation, formation or organization of a Person; and (g) any amendment to any of the foregoing.

"Outstanding Invoices" means the invoices issued by Cytovance to GTBP under the SOWs prior to the Signing Date, having an aggregate outstanding balance of $6,502,535.50 (the "Outstanding Balance"), as set forth in Exhibit D.

"Per Share Purchase Price" means the closing price per share of GTBP Common Stock on the date of issuance hereunder, as reported on the principal U.S. national securities exchange on which such shares are listed and traded on such date, or, if there is no closing price on that date, then on the last preceding date on which such a closing price was reported.

"Permitted Liens" means any and all (a) restrictions, obligations and encumbrances arising under or pursuant to this Agreement, (b) restrictions on transfer arising under applicable securities laws, and (c) Liens or other encumbrances created by or imposed by Cytovance.

"Person" includes any individual, a corporation, an association, a partnership, a trust or estate, a government and any agency or political subdivision thereof, or any other entity.

"Proceeding" means (a) any claim, demand, complaint, action, arbitration, lawsuit, hearing or other proceeding before or filed with a governmental authority, or (b) any investigation, inquiry, charge or audit by a governmental authority.

"Rule 144" has the meaning set forth in Section 8.2(a).

"SEC" has the meaning set forth in Section 5.4.

"Securities Act" has the meaning set forth in Section 5.4.

"Shares" has the meaning set forth in Section 1.2.

"Signing Date" has the meaning set forth in the preamble of this Agreement.

"SOWs" has the meaning set forth in Recital B.

"Subsequent SOW Invoice" means each invoice issued by Cytovance to GTBP under the SOWs following the Signing Date, excluding all materials invoices and stability milestone invoices, which shall be paid in cash in accordance with the terms of the SOWs (as modified by the Change Orders and this Agreement) as set forth in Recital F.

"Subsidiary" or "Subsidiaries" means any corporation, partnership, trust or other entity of which GTBP and/or any of its other Subsidiaries directly or indirectly owns at the time a majority of the outstanding shares or units of any class of equity securities of such corporation, partnership, trust or other entity.

Exhibit 31.1

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: October 31, 2022

By: */s/ Michael Breen*
Name: Michael Breen
Title: Interim Chief Executive Officer,
Chairman and Director

Exhibit 31.2

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: October 31, 2022

By: */s/ Manu Ohri*
Name: Manu Ohri
Title: Chief Financial Officer and Principal Accounting Officer

Exhibit 32.1

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, 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: October 31, 2022

By: */s/ Michael Breen*
Name: Michael Breen
Title: Interim Chief Executive Officer,
Chairman and Director

Exhibit 32.2

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, 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: October 31, 2022

By: */s/ Manu Ohri*
Name: Manu Ohri
Title: Chief Financial Officer and Principal Accounting Officer