

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

FORM 10-Q

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

For the quarterly period ended June 30, 2024.

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

For the transition period from _____ to _____.

Commission File Number 001-40023

GT BIOPHARMA, INC.

(Exact name of registrant as specified in its charter)

Delaware
(State or other jurisdiction of
incorporation or organization)

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

(Address not applicable¹)

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

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

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

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes No

Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T during the preceding 12 months (or for such shorter period that the registrant was required to submit such files). Yes No

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, a smaller reporting company or an emerging growth company. See the definitions of "large accelerated filer," "accelerated filer," "smaller reporting company" and "emerging growth company" in Rule 12b-2 of the Exchange Act.

Large accelerated filer Accelerated filer
Non-accelerated filer Smaller reporting company
Emerging growth company

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act.

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes No

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

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

GT Biopharma, Inc. and Subsidiaries
FORM 10-Q
For the Six Months Ended June 30, 2024
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GT BIOPHARMA, INC. AND SUBSIDIARIES
Condensed Consolidated Balance Sheets

	<u>June 30, 2024</u>	<u>December 31, 2023</u>
	<u>(Unaudited)</u>	
ASSETS		
Current assets		
Cash and cash equivalents	\$ 9,249,000	\$ 1,079,000
Short-term investments	—	12,893,000
Prepaid expenses and other current assets	18,000	84,000
Total Current Assets	9,267,000	14,056,000
Operating lease right-of-use asset	-	53,000
TOTAL ASSETS	\$ 9,267,000	\$ 14,109,000
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities		
Accounts payable	\$ 1,717,000	\$ 4,328,000
Accrued expenses	1,765,000	1,195,000
Current operating lease liability	—	58,000
Warrant liability	277,000	1,052,000
Total Current Liabilities	3,759,000	6,633,000
Stockholders' Equity		
Convertible Preferred stock, par value \$0.01, 15,000,000 shares authorized Series C - 96,230 shares issued and outstanding at June 30, 2024 and December 31, 2023, respectively	1,000	1,000
Common stock, par value \$0.001, 250,000,000 shares authorized, 2,234,328 and 1,380,633 shares issued and outstanding as of June 30, 2024 and December 31, 2023, respectively	2,000	1,000
Additional paid in capital	693,546,000	689,539,000
Accumulated deficit	(688,041,000)	(682,065,000)
Total Stockholders' Equity	5,508,000	7,476,000
TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY	\$ 9,267,000	\$ 14,109,000

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

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

	For The Three Months Ended June 30,		For the Six Months Ended June 30,	
	2024	2023	2024	2023
	(Unaudited)	(Unaudited)	(Unaudited)	(Unaudited)
Operating Expenses:				
Research and development	\$ 1,784,000	\$ 2,095,000	\$ 2,561,000	\$ 3,745,000
Selling, general and administrative (including \$120,000 and \$398,000 from stock compensation granted to officers, directors, and employees during the three months ended June 30, 2024 and 2023, respectively, and \$222,000 and \$905,000 for the six months ended June 30, 2024 and 2023, respectively)	2,122,000	1,526,000	4,436,000	3,541,000
Loss from Operations	<u>(3,906,000)</u>	<u>(3,621,000)</u>	<u>(6,997,000)</u>	<u>(7,286,000)</u>
Other Income (Expense)				
Interest income	105,000	220,000	247,000	384,000
Interest expense	—	(1,000)	—	(213,000)
Change in fair value of warrant liability	117,000	1,387,000	775,000	4,311,000
Gain on extinguishment of debt	—	14,000	—	547,000
Unrealized gain (loss) on marketable securities	1,000	9,000	(1,000)	38,000
Other	(27,000)	—	—	—
Total Other Income	<u>196,000</u>	<u>1,629,000</u>	<u>1,021,000</u>	<u>5,067,000</u>
Net Loss	<u>\$ (3,710,000)</u>	<u>\$ (1,992,000)</u>	<u>\$ (5,976,000)</u>	<u>\$ (2,219,000)</u>
Net Loss Per Share - Basic and Diluted	<u>\$ (2.17)</u>	<u>\$ (1.49)</u>	<u>\$ (3.86)</u>	<u>\$ (1.68)</u>
Weighted average common shares outstanding - basic and diluted	<u>1,711,955</u>	<u>1,339,087</u>	<u>1,546,294</u>	<u>1,321,069</u>

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

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

	<u>Preferred Shares</u>		<u>Common Shares</u>		<u>Additional Paid in Capital</u>	<u>Accumulated Deficit</u>	<u>Total</u>
	<u>Shares</u>	<u>Amount</u>	<u>Shares</u>	<u>Amount</u>			
Balance, March 31, 2024	96,230	\$ 1,000	1,380,633	\$ 1,000	\$ 689,641,000	\$ (684,331,000)	\$ 5,312,000
Issuance of common stock and warrants for cash	-	-	740,000	1,000	2,975,000	-	2,976,000
Cancellation of common stock issued to prior CFO	-	-	(13,902)	-	-	-	-
Issuance of common shares to settle vendor payable	-	-	127,597	-	810,000	-	810,000
Fair value of vested stock options	-	-	-	-	120,000	-	120,000
Net loss	-	-	-	-	-	(3,710,000)	(3,710,000)
Balance, June 30, 2024	<u>96,230</u>	<u>\$ 1,000</u>	<u>2,234,328</u>	<u>\$ 2,000</u>	<u>\$ 693,546,000</u>	<u>\$ (688,041,000)</u>	<u>\$ 5,508,000</u>

	<u>Preferred Shares</u>		<u>Common Shares</u>		<u>Additional Paid in Capital</u>	<u>Accumulated Deficit</u>	<u>Total</u>
	<u>Shares</u>	<u>Amount</u>	<u>Shares</u>	<u>Amount</u>			
Balance, December 31, 2023	96,230	\$ 1,000	1,380,633	\$ 1,000	\$ 689,539,000	\$ (682,065,000)	\$ 7,476,000
Issuance of common stock and warrants for cash	-	-	740,000	1,000	2,975,000	-	2,976,000
Cancellation of common stock issued to prior CFO	-	-	(13,902)	-	-	-	-
Issuance of common shares to settle vendor payable	-	-	127,597	-	810,000	-	810,000
Fair value of vested stock options	-	-	-	-	222,000	-	222,000
Net loss	-	-	-	-	-	(5,976,000)	(5,976,000)
Balance, June 30, 2024	<u>96,230</u>	<u>\$ 1,000</u>	<u>2,234,328</u>	<u>\$ 2,000</u>	<u>\$ 693,546,000</u>	<u>\$ (688,041,000)</u>	<u>\$ 5,508,000</u>

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

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

	<u>Preferred Shares</u>		<u>Common Shares</u>		<u>Additional Paid in Capital</u>	<u>Accumulated Deficit</u>	<u>Total</u>
	<u>Shares</u>	<u>Amount</u>	<u>Shares</u>	<u>Amount</u>			
Balance, March 31, 2023	96,230	\$ 1,000	1,229,424	\$ 1,000	\$ 687,746,000	\$ (682,065,000)	\$ 13,053,000
Private placement of common stock	-	-	-	-	-	-	-
Issuance of common stock for exercise of prefunded warrants	-	-	96,666	-	-	-	-
Initial recognition of fair value of warrant liability	-	-	-	-	-	-	-
Issuance of common shares for services	-	-	-	-	-	-	-
Issuance of common shares to settle vendor payable	-	-	28,566	-	304,000	-	304,000
Fair value of vested stock options	-	-	-	-	398,000	-	398,000
Net loss	-	-	-	-	-	(1,992,000)	(1,992,000)
Balance, June 30, 2023	<u>96,230</u>	<u>\$ 1,000</u>	<u>1,354,656</u>	<u>\$ 1,000</u>	<u>\$ 688,448,000</u>	<u>\$ (676,687,000)</u>	<u>\$ 11,763,000</u>

	<u>Preferred Shares</u>		<u>Common Shares</u>		<u>Additional Paid in Capital</u>	<u>Accumulated Deficit</u>	<u>Total</u>
	<u>Shares</u>	<u>Amount</u>	<u>Shares</u>	<u>Amount</u>			
Balance, December 31, 2022	96,230	\$ 1,000	1,090,748	\$ 1,000	\$ 686,200,000	\$ (674,467,000)	\$ 11,734,000
Private placement of common stock	-	-	120,000	-	6,268,000	-	6,268,000
Issuance of common stock for exercise of prefunded warrants	-	-	96,666	-	-	-	-
Initial recognition of fair value of warrant liability	-	-	-	-	(5,831,000)	-	(5,831,000)
Issuance of common shares for services	-	-	2,449	-	315,000	-	315,000
Issuance of common shares to settle vendor payable	-	-	44,793	-	591,000	-	591,000
Fair value of vested stock options	-	-	-	-	905,000	-	905,000
Net loss	-	-	-	-	-	(2,219,000)	(2,219,000)
Balance, June 30, 2023	<u>96,230</u>	<u>\$ 1,000</u>	<u>1,354,656</u>	<u>\$ 1,000</u>	<u>\$ 688,448,000</u>	<u>\$ (676,687,000)</u>	<u>\$ 11,763,000</u>

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

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

	For The Six Months Ended	
	June 30,	
	2024	2023
	(Unaudited)	(Unaudited)
CASH FLOWS FROM OPERATING ACTIVITIES		
Net loss	\$ (5,976,000)	\$ (2,219,000)
Adjustments to reconcile net loss to net cash used in operating activities:		
Stock based compensation - services	-	315,000
Stock based compensation - officers, directors, and employees	222,000	905,000
Change in fair value of warrant liability	(775,000)	(4,311,000)
Gain on extinguishment of share settled debt	-	(547,000)
Change in operating lease right-of-use assets	53,000	51,000
Unrealized loss (gain) on marketable securities	(1,000)	(38,000)
Changes in operating assets and liabilities:		
Decrease in prepaid expenses	67,000	5,000
Increase (Decrease) in accounts payable and accrued expenses	(1,231,000)	1,052,000
(Decrease) in operating lease liability	(58,000)	(54,000)
Net Cash Used in Operating Activities	<u>(7,699,000)</u>	<u>(4,841,000)</u>
CASH FLOWS FROM INVESTING ACTIVITIES		
Sale (purchase) of investments	12,893,000	(4,332,000)
Net Cash Provided by (Used in) Investing Activities	<u>12,893,000</u>	<u>(4,332,000)</u>
CASH FLOWS FROM FINANCING ACTIVITIES		
Proceeds from issuance of common stock and warrants, net	2,976,000	6,268,000
Net Cash Provided by Financing Activities	<u>2,976,000</u>	<u>6,268,000</u>
Net Increase (Decrease) in Cash and Cash Equivalents	8,170,000	(2,905,000)
Cash at Beginning of Period	1,079,000	5,672,000
Cash at End of Period	<u>\$ 9,249,000</u>	<u>\$ 2,767,000</u>
<u>SUPPLEMENTAL DISCLOSURES OF CASH FLOW INFORMATION:</u>		
Cash paid during the year for:		
Interest	\$ -	\$ -
Income taxes	\$ -	\$ -
<u>SUPPLEMENTAL DISCLOSURES OF NON-CASH INVESTING AND FINANCING ACTIVITIES</u>		
Initial recognition of fair value of warrant liability	\$ -	\$ 5,831,000
Fair value of common stock issued to a vendor to settle accounts payable	\$ 810,000	\$ 591,000

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

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

Note 1 – Organization and Going Concern Analysis

Organization

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

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

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

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

Going Concern Analysis

The Company does not have any product candidates approved for sale and have not generated any revenue from its product sales. The Company has sustained operating losses since inception, and expects such losses to continue into the foreseeable future. Historically, the Company has financed its operations through public and private sales of common stock, issuance of preferred and common stock, issuance of convertible debt instruments, and strategic collaborations. For the six months ended June 30, 2024, the Company recorded a net loss of approximately \$6.0 million and used cash in operations of \$7.7 million. As of June 30, 2024, the Company had a cash and cash equivalents and short-term investments balance of \$9.2 million, working capital of \$5.8 million, and stockholders’ equity of \$5.5 million.

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

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

Note 2 – Summary of Significant Accounting Policies

Basis of Presentation and Principles of Consolidation

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

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

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

Accounting Estimates

The preparation of financial statements in conformity with GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of revenues and expenses during the reporting period. Actual results could differ from those estimates. Significant estimates include management's estimates for continued liquidity, accruals for potential liabilities, assumptions used in deriving the fair value of derivative liabilities, valuation of equity instruments issued for debt and services and realization of deferred tax assets.

Cash Equivalents and Short-Term Investments

The Company considers highly liquid investments with maturities of three months or less at the date of acquisition as cash equivalents in the accompanying unaudited condensed consolidated financial statements. At June 30, 2024 total cash equivalents which consist of money market funds and US treasuries, amounted to approximately \$7.6 million. At December 31, 2023 total cash equivalents which consist of money market funds, amounted to approximately \$443,000.

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

Fair Value of Financial Instruments

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

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

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

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

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

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

The carrying amount of the Company's warrant liability of \$277,000 and \$1.1 million at June 30, 2024 and December 31, 2023, respectively, was based on Level 3 measurements.

Warrant Liability

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

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

Common Stock (February 2024 Reverse Stock Split)

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

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

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

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

Stock-Based Compensation

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

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

Research and Development Expenses

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

Leases

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

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

Net Loss Per Share

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

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

	June 30, 2024 (Unaudited)	June 30, 2023 (Unaudited)
Options to purchase common stock	126,265	124,599
Warrants to purchase common stock	1,133,762	304,962
Total anti-dilutive securities	1,260,027	429,561

Concentration

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

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

Segments

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

Management has determined that the Company has one consolidated operating segment. The Company’s reporting segment reflects the manner in which its chief operating decision maker reviews results and allocates resources. The Company’s reporting segment meets the definition of an operating segment and does not include the aggregation of multiple operating segments.

Recent Accounting Pronouncements

In November 2023, the FASB issued ASU No. 2023-07, “*Segment Reporting (Topic 280): Improvements to Reportable Segment Disclosures*” (“ASU 2023-07”), which introduces new reportable segment disclosure requirements related to significant segment expenses and also expands reportable segment disclosure requirements for interim reporting. The amendment will require public entities to disclose significant segment expenses that are regularly provided to the chief operating decision maker and are included within each reportable segment’s profits and losses. ASU 2023-07 is effective for fiscal years beginning after December 15, 2023, and interim periods within fiscal years beginning after December 15, 2024, with early adoption permitted. We are in the process of evaluating the impact that ASU 2023-07 will have on our segment related disclosures.

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

Note 3 – Fair Value of Financial Instruments

Financial Assets

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

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

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

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

	June 30, 2024 (Unaudited)			
	Fair Value	Level 1	Level 2	Level 3
Cash equivalents:				
Money market funds	\$ 1,037,000	\$ 1,037,000	\$ —	\$ —
US treasuries	6,570,000	—	6,570,000	—
Short-term investments:				
US treasuries	—	—	—	—
Total financial assets	<u>\$ 7,607,000</u>	<u>\$ 1,037,000</u>	<u>\$ 6,570,000</u>	<u>\$ —</u>

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

Warrant Liability

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

Note 4 – Accounts Payable and Accrued Expenses, and Related Party

Accounts payable consists of the following:

	As of June 30, 2024 (Unaudited)	As of December 31, 2023
Accounts payable to Cytovance, a related party ¹	\$ 842,000	\$ 3,515,000
Other accounts payable	875,000	813,000
Total accounts payable	<u>\$ 1,717,000</u>	<u>\$ 4,328,000</u>

Accrued Expenses consists of the following:

	As of June 30, 2024 (Unaudited)	As of December 31, 2023
Accrued expenses, University of Minnesota	\$ 862,000	\$ 192,000
Other accrued expenses	903,000	1,003,000
Total accrued expenses	<u>\$ 1,765,000</u>	<u>\$ 1,195,000</u>

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

See Note 8 – Commitments and Contingencies, Significant Agreements.

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

	Six Months Ending	
	June 30, 2024 (Unaudited)	June 30, 2023 (Unaudited)
Beginning balance	\$ 3,515,000	\$ 2,283,000
Invoices, net	778,000	2,877,000
Payments in cash	(2,641,000)	(1,130,000)
Payments in common stock, at fair value	(810,000)	(1,120,000)
Ending balance	<u>\$ 842,000</u>	<u>\$ 2,910,000</u>

University of Minnesota

See Note 8 – Commitments and Contingencies, Significant Agreements.

Note 5 – Warrant Liability

2023 Warrants

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

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

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

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

	2023 Warrants	
	June 30, 2024 (Unaudited)	December 31, 2023 (Unaudited)
Stock price	\$ 2.83	\$ 7.80
Risk-free interest rate ¹	4.43%	4.26%
Expected volatility ²	116%	115%
Expected life (in years) ³	3.5 - 4.0	4.25
Expected dividend yield ⁴	—	—
Fair value of warrants	<u>\$ 277,000</u>	<u>\$ 1,050,00</u>

¹ Based on rates established by the Federal Reserve Bank

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

³ Determined by the remaining contractual life of the derivative instrument

⁴ Based on no dividends paid or expected to be paid

2020 Warrants

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

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

	2020 Warrants	
	June 30, 2024 (Unaudited)	December 31, 2023
Stock price	\$ 2.83	\$ 7.80
Risk-free interest rate ¹	5.09%	4.54%
Expected volatility ²	116%	89%
Expected life (in years) ³	1.0	1.6
Expected dividend yield ⁴	—	—
Fair value of warrants	\$ —	\$ 2,000

Warrant Liability

The details of warrant liability transactions were as follows:

	Six Months Ending	
	June 30, 2024 (Unaudited)	June 30, 2023 (Unaudited)
Beginning balance	\$ 1,052,000	\$ —
Issuance of warrants at fair value	—	5,831,000
Change in fair value	(775,000)	(4,311,000)
Extinguishment	—	—
Ending balance	\$ 277,000	\$ 1,520,000

Note 6 – Stockholders’ Equity

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

Common Stock

2024 Common Stock Offering

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

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

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

2023 Private Placement of Common Stock

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

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

Common Stock Issued for Services

During the six months ended June 30, 2023, and pursuant to the vesting term of a 2021 agreement, the Company issued 2,449 shares of common stock with a fair value of \$315,000 to members of the Company's Board of Directors (the "Board"), employees, and consultants. The shares were valued at the respective date of the agreements.

Preferred Stock

Series C Preferred Stock

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

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

Series K Preferred Stock

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

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

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

Note 7 – Common Stock Warrants and Options

Common Stock Warrants

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

	Six Months Ended June 30, 2024	
	Number of Warrants	Weighted Average Exercise Price
Warrants outstanding at December 31, 2023	304,962	\$ 63.30
Granted	828,800	4.47
Forfeited/cancelled	—	—
Exercised	—	—
Warrants outstanding at June 30, 2024	<u>1,133,762</u>	<u>\$ 20.28</u>
Warrants exercisable at June 30, 2024	<u>1,133,762</u>	<u>\$ 20.28</u>

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

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

Warrants Outstanding and Exercisable as of June 30, 2024					
Range of Exercise Price	Number Outstanding	Weighted Average Remaining Contractual Life (Years)	Weighted Average Exercise Price		Weighted Average Exercise Price
\$ 4.35	740,000	4.9	\$ 4.35		4.35
5.4375	88,800	4.9			5.4375
30.00	216,666	4.0			30.00
37.50	13,000	3.5			37.50
102.00	1,867	1.0			102.00
165.00	73,429	1.6			165.00
	<u>1,133,762</u>	4.5			<u>20.28</u>

Common Stock Options

In April 2022 the Company established the 2022 Omnibus Incentive Plan (the "Plan"). The Plan was approved by our Board and stockholders. The purpose of the Plan is to grant stock and options to purchase our common stock, and other incentive awards, to our employees, directors, and key consultants. The maximum number of shares of common stock that may be issued pursuant to awards granted under the Plan is 166,667. The shares of our common stock underlying cancelled and forfeited awards issued under the Plan may again become available for grant under the Plan. As of June 30, 2024, there were 7,966 shares available for grant under the Plan.

The following table summarizes stock option transactions for the six months ended June 30, 2024:

	Six Months Ended June 30, 2024	
	Number of Options	Weighted Average Exercise Price
Options outstanding at December 31, 2023	126,265	\$ 40.15
Granted	—	—
Forfeited/cancelled	—	—
Exercised	—	—
Options outstanding at June 30, 2024	<u>126,265</u>	<u>\$ 40.15</u>
Options exercisable at June 30, 2024	<u>126,265</u>	<u>\$ 40.15</u>

The weighted average remaining contractual life of all options outstanding, and all options vested and exercisable as of June 30, 2024 was 8.43 years. Furthermore, all options outstanding and all options vested and exercisable as of June 30, 2024 had an exercise price greater than the market price of the Company's common stock, which resulted in no intrinsic value.

The total fair value of options that vested during the six months ended June 30, 2024 and 2023, was \$222,000 and \$905,000, respectively, and is included in selling, general and administrative expense in the accompanying unaudited condensed consolidated statements of operations. As of June 30, 2024, all outstanding stock options were fully vested and exercisable and there was no accompanying unvested compensation expense.

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

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

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

Stock Options Outstanding and Exercisable as of June 30, 2024				
Range of Exercise Price	Number Outstanding	Weighted Average Remaining Contractual Life (Years)	Weighted Average Exercise Price	
\$ 10.50	16,666	8.8	\$ 10.50	
25.50	66,667	8.6	25.50	
74.40	42,932	8.0	74.40	
	<u>126,265</u>			

Note 8 – Commitments and Contingencies

Litigation

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

Ohri Matter

On July 22, 2024, the Company filed an AAA Arbitration Demand against Manu Ohri, its former Chief Financial Officer. In the Demand, the Company asserts claims against Mr. Ohri for breach of his fiduciary duties and breach of contract and seeks a declaratory judgment providing that the Company may characterize Mr. Ohri's termination as "for cause" under his Employment Agreement, and that the Company may revoke the Separation Agreement entered into between the Company and Mr. Ohri prior to the Company learning of Mr. Ohri's breaches. In addition to the declaratory judgment, the Company seeks damages arising from Mr. Ohri's violations, and attorneys' fees and any forum and arbitration fees. Mr. Ohri's response to the Company's Demand is due August 20, 2024. At this early stage in the proceedings the Company is not able to determine the probability of the outcome of this matter or a range of reasonably expected losses, if any.

Berk Matter

On November 14, 2023, former interim Chief Executive Officer, Dr. Gregory Berk filed a lawsuit in the US District Court for the District of Massachusetts alleging that the Company discriminated and retaliated against Dr. Berk for engaging in protected whistleblowing activity in violation of the Sarbanes Oxley Act ("SOX"). The Parties are proceeding with litigating Dr. Berk's SOX claim. The Company is vigorously defending this matter and believes it to be without merit. At this early stage in the proceedings the Company is not able to determine the probability of the outcome of this matter or a range of reasonably expected losses, if any.

TWF Global Matter

On May 24, 2023, TWF Global, LLC ("TWF") filed a Complaint in the California Superior Court for the County of Los Angeles naming the Company as defendant. The Complaint alleges that TWF is the holder of two Convertible Promissory Notes ("Notes") and that the Company did not deliver shares of common stock due on conversion in February 2021. TWF was seeking per diem liquidated damages based on the terms of alleged Notes. On July 14, 2023, the Company filed a motion to dismiss for improper forum because the terms of the Notes, as alleged, require disputes to be filed in New York state and federal courts. TWF voluntarily dismissed its Complaint before the California Superior Court of Los Angeles without prejudice. The Company subsequently filed a Summons and Complaint for Interpleader against TWF and Z-One LLC before the Supreme Court of the State of New York County of New York, asking the Supreme Court to determine if the Company's shares of common stock are properly registered to TWF or Z-One LLC, as both of these entities have made conflicting demands for registration of the shares of common stock. On February 5, 2024, the Company filed a motion for entry of default against TWF, seeking an order directing the Company to register the shares of common stock in the name of Z-One and that the Company be released from all associated liability and claims. The Court denied the motion without prejudice and will reconsider the motion without further briefing upon the filing of a party affidavit. Z-One has filed a concurrent motion to dismiss of the action, representing that Z-One and TWF have settled their dispute over the entitlement to the Company's shares of common stock. The Company believes that any claims related to the Notes are without merit and will continue to defend vigorously against these claims.

Handelman Matter

On May 13, 2022, the Company made an arbitration demand upon Michael Handelman, its former Chief Financial Officer, asserting that he breached his fiduciary duty by misappropriating Company funds and shares of common stock, among other things. The Company seeks among other relief, monetary damages estimated at \$470,000; the return of 13,902 shares of our common stock received without authorization; and an award of the Company's attorneys' fees and any forum and arbitration fees. In May 2024, the Arbitrator issued the final award in favor of the Company which awarded the Company its legal fees in the amount of \$473,000 plus costs in the amount of \$19,000 and the return of the disputed 13,902 shares of common stock, which were returned to the Company in June 2024.

Significant Agreements

Cytovance Biologics, Inc., a Related Party

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

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

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

During the six months ended June 30, 2024 and 2023, the Company issued 127,597 and 44,793 shares of common stock to Cytovance to settle accounts payable valued at approximately \$810,000 and \$1,120,000, respectively.

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

As of June 30, 2024 the Company's commitments in relation to unbilled and unaccrued SOWs and any related Change Orders from Cytovance for services that have not yet been rendered as of June 30, 2024, amounted to approximately \$1.5 million.

University of Minnesota

2021 Scientific Research Agreement

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

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

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

2023 Sponsored Research Agreement

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

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

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

2016 Exclusive Patent License Agreement

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

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

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

2021 Exclusive License Agreement

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

The Company recorded an expense classified as research and development of approximately \$145,000 and \$0, pursuant to the 2021 Exclusive License Agreement, for the six months ended June 30, 2024 and 2023, respectively.

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

CAUTIONARY NOTICE REGARDING FORWARD-LOOKING STATEMENTS

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

Organization

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

Overview

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

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

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

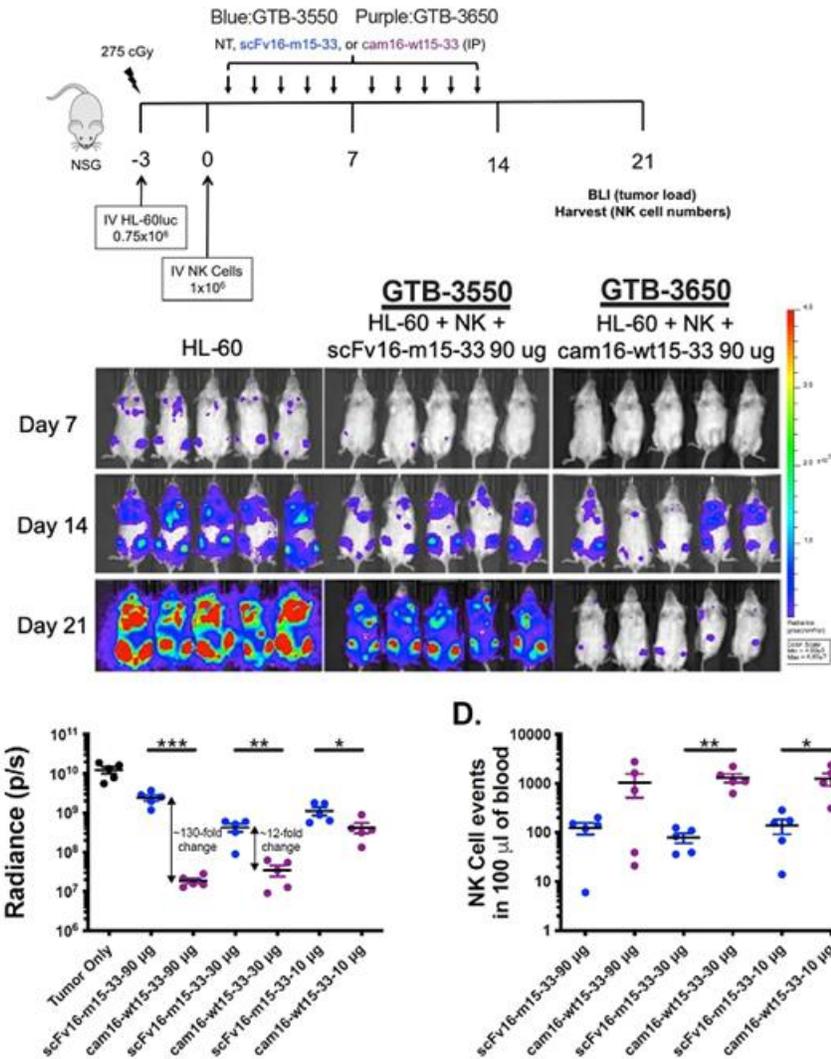
Our product pipeline as of June 30, 2024 is presented below:

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

GTB-3550

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

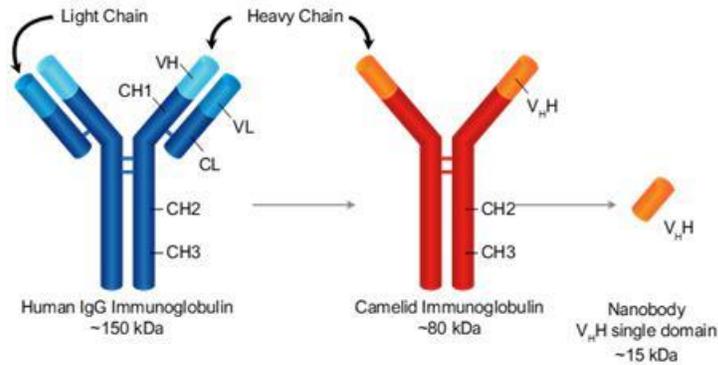
GTB-3550 was replaced by a more potent next-generation camelid nanobody TriKE®, GTB-3650, both targeting CD33 on relapsed/refractory AML and high-risk MDS. The pivot from GTB-3550 to GTB-3650 in our clinical development was based on a solid preclinical foundation that showed markedly enhanced potency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



Second Generation TriKE@s Utilize Camelid Nanobody Technology

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

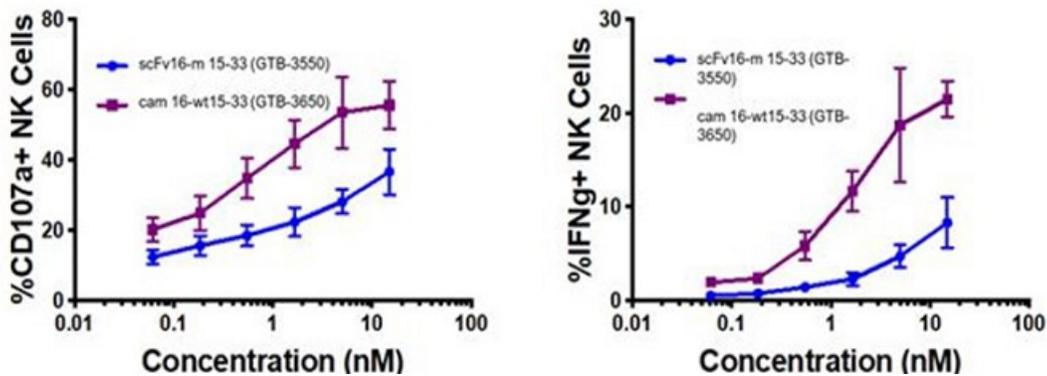
To develop second generation TriKE®s, we designed a new humanized CD16 engager derived from a single-domain antibody. While scFvs consist of a heavy and a light variable chain joined by a linker, single-domain antibodies consist of a single variable heavy chain capable of engaging without the need of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



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

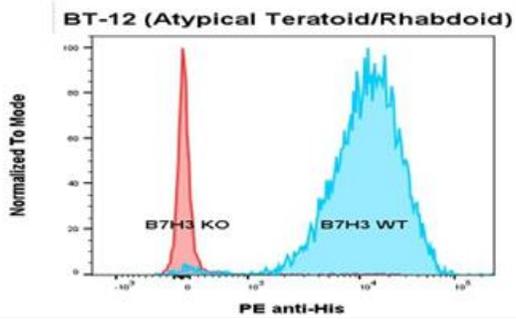
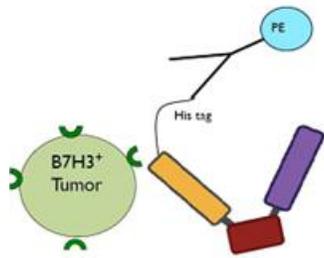
CD33+ HL60 Targets in Killing Assays

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



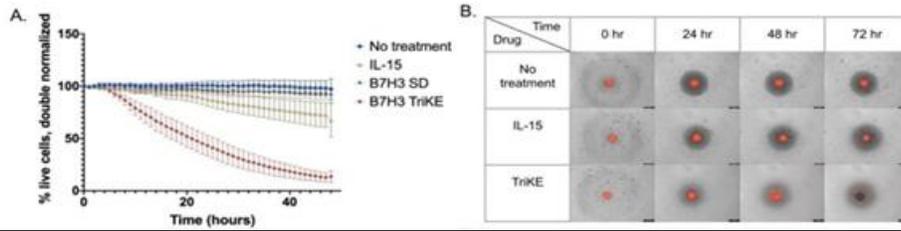
GTB-3650

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



GTB-5550

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



Critical Accounting Policies and Estimates

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

Use of Estimates

The preparation of financial statements in conformity with GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of revenues and expenses during the reporting period. Significant estimates include accruals for potential liabilities, assumptions used in deriving the fair value of warrant liabilities, valuation of equity instruments issued for services, and valuation of deferred tax assets. Actual results could differ from those estimates.

Warrant Liability

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

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

Stock-Based Compensation

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

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

Results of Operations

Comparison of the Three and Six Months Ended June 30, 2024 and 2023

Operating Expenses

	Three Months Ended June 30,			
	2024	2023	\$ Change	% Change
Operating Expenses:				
Research and development	\$ 1,784,000	\$ 2,095,000	\$ (311,000)	(15)%
Selling, general and administrative	2,002,000	1,128,000	874,000	77%
Stock compensation	120,000	398,000	(278,000)	(70)%
Total Operating Expenses	\$ 3,906,000	\$ 3,621,000	\$ 285,000	8%

	Six Months Ended June 30,			
	2024	2023	\$ Change	% Change
Operating Expenses:				
Research and development	\$ 2,561,000	\$ 3,748,000	\$ (1,187,000)	(32)%
Selling, general and administrative	4,214,000	2,633,000	1,581,000	60%
Stock compensation	222,000	905,000	(683,000)	(75)%
Total Operating Expenses	\$ 6,997,000	\$ 7,286,000	\$ (289,000)	(4)%

Research and Development Expenses

Research and development expenses decreased by \$311,000 and \$1.2 million, for the three and six months ended June 30, 2024 and 2023, respectively, primarily due to a decrease in project materials costs, partially offset by an increase in scientific research costs.

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

Selling, General, and Administrative Expenses

Selling, general, and administrative expenses increased by \$874,000 and \$1.6 million, for the three and six months ended June 30, 2024 and 2023, respectively, primarily due to an increase in legal and professional fees.

Other Income (Expense)

	Three Months Ended June 30,			
	2024	2023	\$ Change	% Change
Other Income (Expense):				
Interest income	\$ 105,000	\$ 220,000	\$ (115,000)	(52)%
Interest expense	—	(1,000)	1,000	100%
Change in fair value of warrant liability	117,000	1,387,000	(1,270,000)	(92)%
Gain on extinguishment of debt	—	14,000	(14,000)	(100)%
Unrealized gain (loss) on marketable securities	1,000	9,000	(8,000)	(89)%
Other	(27,000)	—	(27,000)	—%
Total Other Income (Expense)	<u>\$ 196,000</u>	<u>\$ 1,629,000</u>	<u>\$ (1,433,000)</u>	<u>(88)%</u>

	Six Months Ended June 30,			
	2024	2023	\$ Change	% Change
Other Income (Expense):				
Interest income	\$ 247,000	\$ 384,000	\$ (137,000)	(36)%
Interest expense	—	(213,000)	213,000	100%
Change in fair value of warrant liability	775,000	4,311,000	(3,536,000)	(82)%
Gain on extinguishment of debt	—	547,000	(547,000)	(100)%
Unrealized gain (loss) on marketable securities	(1,000)	38,000	(39,000)	(103)%
Other	—	—	—	—%
Total Other Income (Expense)	<u>\$ 1,021,000</u>	<u>\$ 5,067,000</u>	<u>\$ (4,046,000)</u>	<u>(80)%</u>

Interest Income

Interest income decreased by \$115,000 and \$137,000 for the three and six months ended June 30, 2024 compared to the same prior year periods, respectively, primarily due to lower short term investment balances.

Interest Expense

Interest expense decreased by \$213,000 for the six months ended June 30, 2024 compared to the same prior year periods, respectively. The interest expense for the six months ended June 30, 2023 was due to the financing costs incurred associated with warrants accounted as warrant liability sold during the six months ended June 30, 2023, which did not recur in the current period.

Change in Fair Value of Warrant Liability

The change in fair value of warrant liability decreased by \$1.3 million and \$3.5 million for the three and six months ended June 30, 2024 compared to the same prior year periods, respectively, resulting from a reduction in our warrant liability due to the decline in the Company's stock price at June 30, 2024 as compared to the prior comparable periods.

Gain on Extinguishment of Debt

Gain on extinguishment of debt decreased by \$14,000 and \$547,000 for the three and six months ended June 30, 2024 compared to the same prior year periods, respectively. The gain on extinguishment of debt for the six months ended June 30, 2023 resulted from share settlements of a greater amount of vendor accounts payable than the fair value of the shares on the date of settlement, there were no similar transactions during the current period.

Net Loss

	Three Months Ended June 30,			
	2024	2023	\$ Change	% Change
Net Loss	<u>\$ (3,710,000)</u>	<u>\$ (1,992,000)</u>	<u>\$ (1,718,000)</u>	<u>(86)%</u>

	Six Months Ended June 30,			
	2024	2023	\$ Change	% Change
Net Loss	<u>\$ (5,976,000)</u>	<u>\$ (2,219,000)</u>	<u>\$ (3,757,000)</u>	<u>(169)%</u>

Net loss increased \$1,718,000 for the three months ended June 30, 2024, primarily due to the \$1,270,000 decrease in the change in fair value of warrant liability, as described above.

Net loss increased \$3,757,000 for the six months ended June 30, 2024, primarily due to the \$3,536,000 decrease in the change in fair value of warrant liability and the \$547,000 decrease in the gain on extinguishment of debt, both as described above.

Liquidity and Going Concern Analysis

We do not have any product candidates approved for sale and have not generated any revenue from our product sales. We have sustained operating losses since inception, and we expect such losses to continue into the foreseeable future. Historically, we have financed our operations through public and private sales of common stock, issuance of preferred and common stock, issuance of convertible debt instruments, and strategic collaborations. For the six months ended June 30, 2024, we recorded a net loss of approximately \$6.0 million and used cash in operations of \$7.7 million. As of June 30, 2024, we had a cash and cash equivalents and short-term investments balance of \$9.2 million, working capital of \$5.8 million, and stockholders' equity of \$5.5 million.

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

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

Cash Flows

	Six Months Ended June 30,	
	2024	2023
Consolidated Statements of Cash Flow Data:		
Net cash used in operating activities	\$ (7,699,000)	\$ (4,841,000)
Net cash provided by (used in) investing activities	12,893,000	(4,332,000)
Net cash provided by financing activities	2,976,000	6,268,000
Net increase (decrease) in cash and cash equivalents	8,170,000	(2,905,000)
Cash and cash equivalents, beginning of period	1,079,000	5,672,000
Cash and cash equivalents, end of period	<u>\$ 9,249,000</u>	<u>\$ 2,767,000</u>

Operating Activities

Net cash used in operating activities was \$7.7 million for the six months ended June 30, 2024, and was primarily due to a net loss of \$6.0 million, a decrease in accounts payable and accrued expenses of \$1.2 million, and a decrease in the fair value of warrant liability of \$775,000.

Net cash used in operating activities was \$4.4 million for the six months ended June 30, 2023, and was primarily due to a net loss of \$2.2 million, a decrease in the fair value of warrant liability of \$4.3 million, and partially offset by stock compensation of \$1.2 million and an increase in accounts payable and accrued expenses of \$1.1 million.

Investing Activities

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

Financing Activities

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

Working Capital

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

	As of		
	June 30, 2024	December 31, 2023	Increase/(Decrease)
Current assets	\$ 9,267,000	\$ 14,056,000	\$ (4,789,000)
Current liabilities	\$ 3,579,000	\$ 6,633,000	\$ (2,874,000)
Working capital	\$ 5,508,000	\$ 7,423,000	\$ (1,915,000)

Off-Balance Sheet Arrangements

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

Item 3. Quantitative and Qualitative Disclosures About Market Risk

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

Item 4. Controls and Procedures

Evaluation of Disclosure Controls and Procedures

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

Management’s Report on Internal Control Over Financial Reporting

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

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

Inherent Limitations on the Effectiveness of Controls

Management does not expect that our disclosure controls and procedures or our internal control over financial reporting will prevent or detect all errors and all fraud. A control system, no matter how well conceived and operated, can provide only reasonable, not absolute, assurance that the objectives of the control systems are met. Further, the design of a control system must reflect the fact that there are resource constraints, and the benefits of controls must be considered relative to their costs. Because of the inherent limitations in a cost-effective control system, no evaluation of internal control over financial reporting can provide absolute assurance that misstatements due to error or fraud will not occur or that all control issues and instances of fraud, if any, have been or will be detected.

These inherent limitations include the realities that judgments in decision-making can be faulty and that breakdowns can occur because of a simple error or mistake. Controls can also be circumvented by the individual acts of some persons, by collusion of two or more people, or by management override of the controls. The design of any system of controls is based in part on certain assumptions about the likelihood of future events, and there can be no assurance that any design will succeed in achieving its stated goals under all potential future conditions. Projections of any evaluation of controls effectiveness to future periods are subject to risks. Over time, controls may become inadequate because of changes in conditions or deterioration in the degree of compliance with policies or procedures.

Changes in Internal Control Over Financial Reporting

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

PART II. OTHER INFORMATION

Item 1. Legal Proceedings

Ohri Matter

On July 22, 2024, the Company filed an AAA Arbitration Demand against Manu Ohri, its former Chief Financial Officer. In the Demand, the Company asserts claims against Mr. Ohri for breach of his fiduciary duties and breach of contract and seeks a declaratory judgment providing that the Company may characterize Mr. Ohri's termination as "for cause" under his Employment Agreement, and that the Company may revoke the Separation Agreement entered into between the Company and Mr. Ohri prior to the Company learning of Mr. Ohri's breaches. In addition to the declaratory judgment, the Company seeks damages arising from Mr. Ohri's violations, and attorneys' fees and any forum and arbitration fees. Mr. Ohri's response to the Company's Demand is due August 20, 2024. At this early stage in the proceedings the Company is not able to determine the probability of the outcome of this matter or a range of reasonably expected losses, if any.

Berk Matter

On November 14, 2023, former interim Chief Executive Officer, Dr. Gregory Berk filed a lawsuit in the U.S. District Court for the District of Massachusetts alleging that the Company discriminated and retaliated against Dr. Berk for engaging in protected whistleblowing activity in violation of the Sarbanes Oxley Act ("SOX"). The Parties are proceeding with litigating Dr. Berk's SOX claim. The Company is vigorously defending this matter and believes it to be without merit. At this early stage in the proceedings the Company is not able to determine the probability of the outcome of this matter or a range of reasonably expected losses, if any.

TWF Global Matter

On May 24, 2023, TWF Global, LLC ("TWF") filed a Complaint in the California Superior Court for the County of Los Angeles naming the Company as defendant. The Complaint alleges that TWF is the holder of two Convertible Promissory Notes ("Notes") and that the Company did not deliver shares of common stock due on conversion in February 2021. TWF was seeking per diem liquidated damages based on the terms of alleged Notes. On July 14, 2023, the Company filed a motion to dismiss for improper forum because the terms of the Notes, as alleged, require disputes to be filed in New York state and federal courts. TWF voluntarily dismissed its Complaint before the California Superior Court of Los Angeles without prejudice. The Company subsequently filed a Summons and Complaint for Interpleader against TWF and Z-One LLC before the Supreme Court of the State of New York County of New York, asking the Supreme Court to determine if the Company's shares of common stock are properly registered to TWF or Z-One LLC, as both of these entities have made conflicting demands for registration of the shares of common stock. On February 5, 2024, the Company filed a motion for entry of default against TWF, seeking an order directing the Company to register the shares of common stock in the name of Z-One and that the Company be released from all associated liability and claims. The Court denied the motion without prejudice and will reconsider the motion without further briefing upon the filing of a party affidavit. Z-One has filed a concurrent motion to dismiss of the action, representing that Z-One and TWF have settled their dispute over the entitlement to the Company's shares of common stock. The Company believes that any claims related to the Notes are without merit and will continue to defend vigorously against these claims.

Handelman Matter

On May 13, 2022, the Company made an arbitration demand upon Michael Handelman, our former Chief Financial Officer, asserting that he breached his fiduciary duty by misappropriating Company funds and shares of common stock, among other things. The Company seeks among other relief, monetary damages estimated at \$470,000; the return of 13,902 shares of our common stock received without authorization; and an award of the Company's attorneys' fees and any forum and arbitration fees. In May 2024, the Arbitrator issued the final award in favor of the Company which awarded us legal fees in the amount of \$473,000 plus costs in the amount of \$19,000 and the return of the disputed 13,902 shares of common stock, which were returned to the Company in June 2024.

Item 6. Exhibits

Exhibit	Description	Filed Herewith	Form	Number	SEC File No.	Filing Date
3.1	Restated Certificate of Incorporation as filed in Delaware September 10, 1996 and as thereafter amended through March 1, 2002		10-KSB	3.A	000-08092	4/1/2002
3.2	Certificate of Amendment to the Restated Certificate of Incorporation of GT Biopharma, Inc., dated February 9, 2011		10-K	3.2	000-08092	3/31/2011
3.3	Certificate of Amendment to the Restated Certificate of Incorporation of GT Biopharma, Inc., effective as of July 19, 2017		8-K/A	3.1	000-08092	3/15/2018
3.4	Certificate of Amendment to the Restated Certificate of Incorporation of GT Biopharma, Inc., effective as of February 10, 2021		8-K	3.1	001-40023	2/11/2021
3.5	Certificate of Amendment to Restated Certificate of Incorporation of the Registrant effective June 13, 2022		10-K	3.5	001-40023	3/30/2023
3.6	Certificate of Amendment to Restated Certificate of Incorporation of the Registrant effective February 1, 2024		8-K	3.1	001-40023	2/1/2024
3.7	Amended and Restated Bylaws of GT Biopharma, Inc. effective November 3, 2022		8-K	3.1	001-40023	11/9/2022
4.1	Certificate of Designation of Preferences, Rights and Limitations of Series J-1 Preferred Stock of GT Biopharma, Inc., dated April 3, 2019		8-K	3.1	000-08092	4/4/2019
4.2	Certificate of Designation of Preferences, Rights and Limitations of Series K Preferred Stock of GT Biopharma, Inc. dated April 3, 2019		10-K	4.2	001-40023	4/16/2021
4.3	Form of Common Warrant		8-K	4.1	001-40023	5/23/2024
10.1	Amendment No. 1 to Settlement and Investment Agreement, dated as of April 25, 2024, by and between GT Biopharma, Inc. and Cytovance Biologics, Inc.		8-K	10.1	001-40023	4/30/2024
10.2	Amended and Restated Exclusive Patent License Agreement with the Regents of the University of Minnesota, dated May 13, 2024	X				
10.3	Sponsored Research Agreement with the Regents of the University of Minnesota dated May 20, 2024	X				
10.4	Form of Securities Purchase Agreement, dated May 21, 2024		8-K	10.1	001-40023	5/23/2024
10.5	Form of Placement Agency Agreement, dated May 21, 2024		8-K	10.2	001-40023	5/23/2024
10.6	Employment Agreement between the Company and Alan Urban, dated as of June 7, 2024		8-K	10.1	001-40023	6/7/2024
31.1	Certification of Principal Executive Officer pursuant to Rule 13a-14 and Rule 15d-14(a), promulgated under the Securities and Exchange Act of 1934, as amended.	X				
31.2	Certification of Principal Executive Officer pursuant to Rule 13a-14 and Rule 15d-14(a), promulgated under the Securities and Exchange Act of 1934, as amended.	X				
32.1	Certification of Principal Executive Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to section 906 of the Sarbanes-Oxley Act of 2002*	X				
32.2	Certification of Principal Executive Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to section 906 of the Sarbanes-Oxley Act of 2002*	X				
101.INS	Inline XBRL Instance Document.	X				
101.SCH	Inline XBRL Taxonomy Extension Schema Document.	X				
101.CAL	Inline XBRL Taxonomy Extension Calculation Linkbase	X				
101.DEF	Inline XBRL Taxonomy Extension Definition Linkbase	X				
101.LAB	Inline XBRL Taxonomy Extension Label Linkbase Document.	X				
101.PRE	Inline XBRL Taxonomy Extension Presentation Linkbase	X				
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)	X				

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

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned thereunto duly authorized.

GT BIOPHARMA, INC.

Dated: August 14, 2024

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

Dated: August 14, 2024

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

Execution

OTC Agreement No.: A-2022-1707
OTC Case No.(s): 2020-079, 2020-050, 2020-115, 2020-111**AMENDED AND RESTATED EXCLUSIVE PATENT LICENSE AGREEMENT**

THIS AMENDED AND RESTATED EXCLUSIVE PATENT LICENSE AGREEMENT {"Agreement" or "AREPLA") is made by and between Regents of the University of Minnesota, a constitutional corporation under the laws of the state of Minnesota, having a place of business at 200 Oak Street, SE, Suite 280, Minneapolis, Minnesota 55455 (the "University"), and the Licensee identified below. The University and the Licensee agree that:

The Terms and Conditions of Amended and Restated Exclusive Patent License Agreement attached hereto as **Exhibit A** ("Terms and Conditions") are incorporated herein by reference in their entirety. Capitalized terms used in this Agreement (other than the terms, "Section," "Subsection", and Section, Subsection, and table headings) without definition have the meanings given to them in the Terms and Conditions. The section numbers used in the parentheses below correspond to the section numbers in the Terms and Conditions.

- 1. LICENSEE (§1.7):** GT BioPharma, Inc., a corporation under the laws of Delaware, having its principal offices at 8000 Marina Blvd., Suite 100, Brisbane, CA 94005.
- 2. FIELD(S) OF USE (§1.4):**
 - 2.1** For the Legacy Patent Family listed in Section 5.1 and 5.2, and the Restatement Family listed in Exhibit B: All
 - 2.2** For the Clec12A Family listed Exhibit C: Human therapeutic use in a Protein Biologic in the form of a:
 - 2.2.1** TriKE covered by the Legacy Patent Family;
 - 2.2.2** TriKE not covered by the Legacy Patent Family;
 - 2.2.3** BiKE; and
 - 2.2.4** BiTE,

For clarification and not meant to be an exhaustive list, and solely with respect to the licenses granted to the Clec12A Family, the following are not within the Field of Use and are not included in this Agreement and no rights are granted to Licensee for:

- a. Any non-human therapeutic use in a Protein Biologic;
- b. Any non-therapeutic use in a Protein Biologic;
- c. Any cell based (e.g., T cells, NK cells, Myeloid cells, etc.) delivery or production of a protein covered for any therapeutic or non-therapeutic use;
- d. Any nucleic acid-based delivery or production of a protein for any therapeutic or non-therapeutic use except for the manufacture of the therapeutic products set forth in Sections 2.2.1 through 2.2.4 above; and
- e. Any virus-based delivery or production of a protein for any therapeutic or non-therapeutic use except for the manufacture of the therapeutic products set forth in Sections 2.2.1 through 2.2.4 above.

- 3. TERRITORY (§1.16):** Worldwide, except for territories in which Licensee has elected not to pay to the University Patent Related Expenses.
- 4. KEY DATES:**
 - 4.1 Prior Agreement Effective Date:** Date of the last signature of the Prior Agreement.
 - 4.2 Restatement Date:** Date of the last signature of this Agreement.

5. LICENSED PATENTS (§1.5) AND TECHNICAL INFORMATION (IF ANY)**5.1 Legacy Patents(s):**

Patent No.	Country	Issue date	Title
11,098,100	US	8/24/2021	Therapeutic compounds and methods (UM20150302)
11,098,101	US	8/24/2021	Therapeutic compounds and methods (UM20150302)
2016336451	Australia	10/12/2023	Therapeutic compounds and methods (UM20150302)
7274781	Japan	5/9/2023	Therapeutic compounds and methods (UM20150302)
389194	Mexico	1/6/22	Therapeutic compounds and methods (UM20150302)
258931	Israel	12/2/2022	Therapeutic compounds and methods (UM20150302)
2770001	Russia	4/14/2022	Therapeutic compounds and methods (UM20150302)

5.2 Legacy Patent Applications:

Application No.	Country	Filing Date	Status	Title
62/237,835 PRV	USA	10/6/2015	Expired	Therapeutic compounds and methods (UM20150302)
PCT/US2016/055722	PCT	10/6/2016	Expired	Therapeutic compounds and methods (UM20150302)
17/396,127 (CON)	USA	8/6/2021	Pending	Therapeutic compounds and methods (UM20150302)
16/561,627 (CON)	USA	9/5/2021	Abandoned	Therapeutic compounds and methods
2023233318 (DIV)	Australia	10/6/2016	Pending	Therapeutic compounds and methods (UM20150302)
16854310.6	EPO	10/6/2016	Abandoned	Therapeutic compounds and methods (UM20150302)
22154076.8 (DIV)	EPO	10/6/2016	Pending	Therapeutic compounds and methods (UM20150302)
42023069761.7 (DIV)	HK	3/9/2023	Pending	Therapeutic compounds and methods (UM20150302)
2018-517586	Japan	10/6/2016	Pending	Therapeutic compounds and methods (UM20150302)
2023-071386 (DIV)	Japan	4/25/2023	Pending	Therapeutic compounds and methods (UM20150302)
11201802794P	Singapore	10/6/2016	Pending	Therapeutic compounds and methods (UM20150302)
10201912792Y	Singapore	12/20/2019	Pending	Therapeutic compounds and methods (UM20150302)

201847015467	India	4/24/2018	Pending	Therapeutic compounds and methods (UM20150302)
3,001,185	Canada	5/24/2018	Pending	Therapeutic compounds and methods (UM20150302)
201680071410.2	China	6/16/2018	Pending	Therapeutic compounds and methods (UM20150302)
19122739.6	Hong Kong	4/23/2019	Pending	Therapeutic compounds and methods (UM20150302)
BR 112018006811-0	Brazil	10/16/2018	Pending	Therapeutic compounds and methods (UM20150302)
1020180057715	South Korea	10/6/2016	Pending	Therapeutic compounds and methods (UM20150302)

5.3 Restatement Patent Applications:

The Restatement Patent Applications are set forth hereto on **Exhibit B**.

5.4 Legacy Patent Family, Restatement Family and Clec12A Family Defined. The Legacy Patents set forth in Section 5.1 hereof and the Legacy Patent Applications set forth in Section 5.2 hereof are collectively be referred to as the "**Legacy Patent Family**". The Restatement Patent Applications referenced in Section 5.3 and listed in Exhibit B hereof are collectively be referred to as the "**Restatement Patent Family**". The Clec12A Patent Applications listed in Exhibit C hereof are collectively referred to as the "**Clec12A Family**".

5.5 Technical Information: None.

6. PATENT-RELATED EXPENSES (§1.11 & 6.3): During the Term as provided in Section 6.3 of the Terms and Conditions, Licensee shall reimburse University for Patent Related Expenses incurred by University after the Restatement Date of the AREPLA for the Legacy Patent Family, the Restatement Patent Family and the Clec12A Family. The aggregate unreimbursed Patent Related expenses as of the AREPLA Restatement Date for the Legacy Patent Family and Restatement Patent Family under the Prior Agreement are \$19,855.57. Payment in full of such amount will satisfy all Licensee's patent expense reimbursement obligations under the Prior Agreement.

7. SUBLICENSE RIGHTS (§3.1):

Yes

8. FEDERAL GOVERNMENT RIGHTS (§3.2.4):

Yes

9. PERFORMANCE MILESTONES (§5.1):

9.1 Legacy Patent Family. The Licensee shall achieve the following milestones with respect to the Legacy Patent Family:

9.1.1 Perform First dosing of a patient In a Phase I clinical trial for a Licensed Product within 36 months from the Restatement Date.

9.1.2 Perform the first dosing of a patient in a Phase II clinical trial for a Licensed Product within 60 months from the Restatement Date.

9.1.3 Perform the first dosing of a patient in a Phase III clinical trial for a Licensed Product within 96 months from the Restatement Date.

9.1.4 Obtain regulatory approval for commercial sale of a Licensed Product in the Territory within 132 months from the Restatement Date.

9.2 Restatement Patent Family. The Licensee shall achieve the following milestones with respect to the Restatement Patent Family and report their achievement to the University:

9.2.1 Identify a lead candidate for a Licensed Product by December 31, 2028.

9.2.2 Spend at least \$2,000,000 in the development and/or commercialization of a Licensed Product by the 3rd anniversary of the Restatement Date.

9.2.3 If Licensee fails to achieve the milestone in Section 9.2.1 or the milestone in Section 9.2.2 by the prescribed date, Licensee shall Sublicense its rights to a Sublicensee identified by the University under usual and customary business terms within six months of University's notice specifying the Sublicensee.

9.3 Clec12A Family. The Licensee shall inform the University of which Clec12A sequence(s) it plans to develop commercially.

10. COMMERCIALIZATION REPORTS: By March 1 of each year, Licensee will submit a written annual report to University covering the preceding calendar year. The report will include information sufficient to enable University to satisfy reporting requirements of the U.S. Government and/or for University to ascertain progress by Licensee toward meeting this Agreement's diligence requirements. Each report will describe, where relevant: Licensee's progress toward commercialization of Licensed Product, including work completed, key scientific discoveries, summary of work-in-progress, current schedule of anticipated events or milestones, market plans for introduction of Licensed Product, and significant corporate transactions involving Licensed Product. Licensee will specifically describe how each Licensed Product is related to each Licensed Patent. For clarification, the reports required by this Section 10 are distinct from the reports required by Section 6.4 of the Terms and Conditions.

11. PAYMENTS (§6.1): All amounts are non-refundable, and payable as indicated below or as specified in the University's invoice,

11.1 Upfront Payment:

11.1.1 University acknowledges that an upfront payment was made in full under the Prior Agreement for the Legacy Patent Family.

11.1.2 For the addition of the Restatement Patent Family and the Clec12A Family, Licensee shall pay to University an additional upfront payment under this Agreement of \$145,000. within 30 days after the Restatement Date.

11.2 Annual License Fee.

University acknowledges that Licensee paid to University annual fees under the Prior Agreement in an aggregate amount of \$250,000 and is current with such obligation as of the Restatement Date. Licensee shall pay to University an annual license fee as follows:

11.2.1 \$50,000 payable on the first anniversary of the Restatement Date of this Agreement.

11.2.2 \$100,000, payable on the second anniversary of the Restatement Date of this Agreement and on each Anniversary of the Restatement Date thereafter.¹

11.3 Document Fee: None.

¹ For University's internal purposes, \$5,000 of each Annual License Fee received is treated as an annual maintenance fee.

11.4 Running Royalties on Net Sales. Licensee shall pay to the University a royalty on Net Sales of Licensed Products as follows:

11.4.1 Licensed Product from Legacy Patent Family. 4% of Net Sales of Licensed Products covered or claimed by a Valid Claim of a Licensed Patent from the Legacy Patent Family, determined and payable as provided in Section 6.4 of the Terms and Conditions.

11.4.2 Licensed Product from Restatement Patent Family. 1.5% of Net Sales of Licensed Products covered by a Valid Claim of a Licensed Patent from the Restatement Patent Family, determined and payable as provided in Section 6.4 of the Terms and Conditions.

11.4.3 Licensed Product from Clec12A Family. (i) 1% of Net Sales of Licensed Products that meet the definition set forth in Section 2.2.1 above and that are covered by a Valid Claim of a Licensed Patent from the Clec12A Family, or (ii) 2.5% of Net Sales of Licensed Products that meet the definitions set forth in Sections 2.2.2 through 2.2.4 above and that are covered by a Valid Claim of a Licensed Patent from the Clec12A Family, in each case (i) and (ii) determined and payable as provided in Section 6.4 of the Terms and Conditions.

11.4.4 Licensed Product from Legacy Patent Family and Restatement Patent Family. 5% of Net Sales of Licensed Products covered by at least one Valid Claim of the Legacy Patent Family and one Valid Claim of the Restatement Patent Family, determined and payable as provided in Section 6.4 of the Terms and Conditions.

11.4.5 Licensed Product from Legacy Patent Family and Clec12A Family. 5% of Net Sales of Licensed Products that meet the definition set forth in Section 2.2.1 above and that are covered by at least one Valid Claim of the Legacy Patent Family and one Valid Claim of the Clec12A Family, determined and payable as provided in Section 6.4 of the Terms and Conditions.

11.4.6 Licensed Product from New Sponsored Research. Licensee is currently sponsoring research at the University which may result in additional inventions, for which Licensee will have an exclusive option to negotiate a license. If Licensee develops products which are covered by a Licensed Patent under this Agreement and are also covered by the claims in a patent for any inventions developed by the University in connection with Licensee's sponsored research, the maximum aggregate royalty which Licensee will be obligated to pay under this Agreement, any amendment to this Agreement and any license agreement that separately licenses such sponsored research inventions to Licensee will not exceed 6%.

11.4.7 Third Party Royalty Stacking for Running Royalty. If Licensee determines that it is necessary to include additional intellectual property from Third Parties in order to develop, make, have made, use, sell, have sold and import Licensed Products hereunder (i.e., the third party patents have issued claims which would be infringed by the manufacture, use or sale of Licensed Product), Licensee may negotiate and obtain license agreements for such intellectual property and credit up to 50% of the royalty payments made by Licensee under such Third Party license(s) against the royalty payable by Licensee to University hereunder; provided, that Licensee's right to an offset of royalties due hereunder is conditioned upon: (1) prior to offsetting any royalties, Licensee shall first take advantage of any other equivalent offset provision under the Third Party license(s), (2) Licensee shall report the full calculation of any offset hereunder in its royalty reporting, and (3) in no event will the royalties due to University be less than:

- (a) 2% on Net Sales of Licensed Product under Section 11.4.1.
- (b) 0.75% on Net Sales of Licensed Product under Section 11.4.2.
- (c) 0.5% on Net Sales of Licensed Product under Section 11.4.3(i) and 1.25% on Net Sales of Licensed Product under Section 11.4.3(ii).

(d) 2.5% on Net Sales of Licensed Product under Sections 11.4.4 and 11.4.5.

(e) 3% on Net Sales of Licensed Product under Section 11.4.6.

11.5 Annual Minimum Royalties. The aggregate annual minimum amount of royalties owed by the Licensee under Subsection 11.4, commencing on March 1 of the year following the first commercial sale of a Licensed Product (such year, "Year 1" and each subsequent year, "Year 2," Year 3," etc.) are as follows:

11.5.1 \$250,000 annually, commencing on March 1 of Year 1 and continuing through March 1 of Year 2.

11.5.2 \$2,000,000 annually, commencing on March 1 of Year 3 and continuing through March 1 of Year 5.

11.5.3 \$5,000,000 annually, commencing on March 1 of Year 6 continuing throughout the remainder of the Term.

11.5.4 Third Party Stacking for Annual Minimum Royalty. The annual minimum royalty payable by Licensee shall be reduced in proportion to the reduction in the running royalty payable to the University pursuant to Section 11.4 hereof on account of any royalty payments made by Licensee to a Third Party under an additional Third Party license agreement in order to develop, make, have made, use, sell, have sold and import Licensed Products, provided, that in no event shall the annual minimum royalty payable to University be less than fifty percent (50%) of the amounts specified in this Section 11.5.1. By way of example only, and not by way of limitation, if the royalty rate payable by Licensee to University in any given year is reduced from 5% to 4% (i.e., by 20%) on account of royalty payments made by Licensee under a Third-Party license agreement, then the annual minimum royalty payment for such year shall also be reduced by 20%.

11.5.5 Tolling of Annual Minimum Royalty. The annual minimum royalty payments shall be tolled for any period during which Licensee's sales of Licensed Product is substantially and negatively affected by (i) a legal action directly pertaining to the Licensed Product, or (ii) a supply chain interruption or regulatory action directly pertaining to the Licensed Product beyond the reasonable control of Licensee; provided that with respect to (i) and (ii) Licensee will provide reasonable documentation, an opportunity to discuss, and approval by the University prior to reducing any royalty payments due to the University.

11.6 Non-Royalty Sublicense Consideration:

11.6.1 Licensee shall pay to the University 50% of all Non-Royalty Sublicense Consideration received by Licensee prior to the initiation of a Phase I clinical trial.

11.6.2 Licensee shall pay to the University 25% of all Non-Royalty Sublicense Consideration received by Licensee after the initiation of a Phase I clinical trial but prior to the initiation of a Phase III clinical trial.

11.6.3 Licensee shall pay to the University 15% of all Non-Royalty Sublicense Consideration received by Licensee after regulatory approval of the first Licensed Product for commercial sale in North America, the European Union, Japan, or Australia,

11.7 Change of Control Fee: License shall pay to the University \$175,000 upon a Change of Control, payable as provided in Section 12.5 of the Terms and Conditions.

11.8 Performance Milestone Payments: The Licensee shall pay University upon achievement of the following milestones:

11.8.1 Clinical Development Milestones:

- (a) \$350,000 upon dosing of a first human subject in a Phase II clinical trial of the first Licensed Product.
- (b) \$500,000 upon dosing of a first human subject in a Phase III clinical trial for the first three Licensed Products.
- (c) \$500,000 upon filing of an BLA with FDA (or EMEA or an equivalent authority) in any Jurisdiction, for the first three Licensed Products.
- (d) \$1,000,000 following the first commercial sale of a first Licensed Product for human use.
- (e) \$500,000 for the first commercial sale of a second Licensed Product for human use.
- (f) \$250,000 for the first commercial sale of a Licensed Product for any non-human use.

11.8.2 Patent issuance milestone:

- (a) University acknowledges and agrees that the patent issuance milestone has been paid in full.

11.8.3 Sales Milestones (one time):

- (a) \$1,000,000 upon reaching 250 Million dollars in cumulative gross sales of Licensed Products.
- (b) \$5,000,000 upon reaching 500 Million dollars in cumulative gross sales of Licensed Products.

11.9 Equity: None.

11.10 Reduction of Payment Obligations. The University's right to receive consideration under this Agreement may be reduced under the following circumstances:

- 11.10.1** If the University enters into a Corporate Sponsored Research arrangement that results in a Triggering Third Party License as more fully set forth in Section 3.2.2 of the Terms and Conditions; or
- 11.10.2** If the University does not consent to being named a party plaintiff in any enforcement action involving the Licensed Patents resulting in Licensee being unable to abate the infringement thereof, as more fully set forth in Section 7.1 hereof.

12. LICENSEE'S ADDRESS FOR NOTICE (§12.12), Notices will be sent to the Licensee at:

Attn: Michael Breen
Chief Executive Officer
GT BioPharma, Inc.
8000 Marina Blvd., Suite 100, Brisbane, CA 94005
Email: mb@gtbiopharma.com

Licensee's Contact Person for Patent Prosecution Consultation (§4.2,1), The University will, as set forth in this Agreement, communicate with the contact person named below with respect to patent prosecution and maintenance: (Upon ten (10) days prior written notice to the University, the Licensee may change the person designated below)

Lisa A, Halle, J.D., Ph.D, DLA Piper LLP (US)
4365 Executive Drive, Suite 1100
San Diego, California 92121
858.677.1456 T
858.353.4166 C
858.638.5040 F
lisa.halle@us.dlapiper.com

Signature page follows

IN WITNESS WHEREOF, the parties hereto have caused their duly authorized representatives to execute this Agreement.

Regents of the University of Minnesota

By: DocuSigned by:
Richard Huebsch
B0505A62399F440...

Name: Richard Huebsch

Associate Vice President

Date: May 13, 2024 | 3:06 PM PDT

GT BioPharma, Inc.

By: DocuSigned by:
Michael Breen
A84E7E36E0004CF...

Name: Michael Breen

Executive Chairman and Interim Chief Executive Officer

Date: May 13, 2024 | 3:15 PM PDT

UNIVERSITY OF MINNESOTA

EXHIBIT A
Agreement Terms and Conditions

These Terms and Conditions govern and are hereby incorporated into the AREPLA. All section references in these Terms and Conditions refer to provisions in the Terms and Conditions unless explicitly stated otherwise. By way of example, "Section 6.4" refers to Section 6.4 of Terms and Conditions, but reference to "Section 6 of the AREPLA" in the Terms and Conditions refers to Section 6 of the AREPLA.

1. **DEFINITIONS.** For purposes of interpreting the AREPLA, the following terms have the following meanings:

- 1.1 **"Affiliate"** means an entity that controls, is controlled by, or is under common control with the Licensee or the Sublicensee, as the case may be. An entity shall be deemed to have control of the controlled entity if it (i) owns, directly or indirectly, 50% or more of the outstanding voting securities of the controlled entity, or (ii) has the right, power or authority, directly or indirectly, to direct or cause the direction of the policy decisions of the controlled entity, whether by ownership of securities, by representation on the controlled entity's governing body, by contract, or otherwise.
- 1.2 **"BIKE"** shall mean a bispecific NK cell engager composed of an NK cell binding/activating domain (e.g., CD16 or NKG2D or NKp30 binders) operably linked to a target cell targeting domain.
- 1.3 **"BiTE"** shall mean a bispecific T-cell engager composed of a T-cell binding/activating domain (e.g., CD3 binder) operably linked to a target cell targeting domain.
- 1.4 **"Change of Control"** means (i) acquisition of ownership -- either directly or indirectly, by any person or group of the capital stock of Licensee representing more than 50% of either the aggregate ordinary voting power or the aggregate equity value represented by the issued and outstanding capital stock of the Licensee; and/or (ii) the sale of all or substantially all the Licensee's assets and/or business in one transaction or in a series of related transactions, provided that a transaction conducted for the sole purpose of changing the Licensee's domicile, an bona fide equity financing transaction involving Licensee, or an initial public offering of the Licensee's capital stock, shall not constitute a "Change of Control" hereunder.
- 1.5 **"Corporate Sponsored Research"** means research that is directly or indirectly sponsored by, directed by, or conducted for the benefit of a for-profit entity.
- 1.6 **"Exclusive"** means that, subject to Section 3.2, University will not grant further licenses or other rights to the Licensed Technology in the Field of Use in the Territory.
- 1.7 **"Field of Use"** means the field(s) of use described in Section 2 of the AREPLA.
- 1.8 **"Licensed Patent"** means (i) the patent(s) described in Section 5.1 of the AREPLA and (ii) the patent applications described in Sections 5.2 and 5.3 of the AREPLA, along with any issued and unexpired patent(s) issued during the Term that arose out of and claim priority to such patent applications, such as for example, continuations, divisional, continuation-in-part, or foreign applications. "Licensed Patent" also means any reissues or re-examinations of a Licensed Patent that contain one or more Valid Claims directed to Licensed Technology. Any claim of an unexpired Licensed Patent is presumed to be valid unless it has been held to be invalid by a final judgment of a court of competent jurisdictions from which no appeal can be or is taken.
- 1.9 **"Licensed Product(s)"** means any product (or part of a product) or service in the Field of Use: (i) the making, using, importing, selling, offering for sale, marketing, or providing of which, absent this license, infringes, induces infringement, or contributes to infringement, or (ii) that is otherwise covered by a Valid Claim of a Licensed Patent, including by way of clarification, the patent applications described in Sections 5.2 and 5.3 of the AREPLA.

- 1.10** **"Licensee"** means the entity identified in Section 1 of the AREPLA.
- 1.11** **"Licensed Technology"** means technology covered by Licensed Patents.
- 1.12** **"Net Sales"** means all gross amounts invoiced by Licensee, its Affiliates, or Sublicensees from the sale, transfer, or other disposition of Licensed Product to a non-Affiliate Third Party purchaser. Net Sales excludes the following items, but only to the extent these items are commercially reasonable under the circumstances, documented in writing, pertain specifically to the sale of a Licensed Product, are appropriately accounted for under generally accepted accounting principles as consistently applied in the United States (or such accounting principles that are customarily applied in the applicable jurisdiction outside the United States), and were not given in exchange for separate consideration such as investments, loans, data, reciprocal discounts or credits, in-kind consideration, or commitments to purchase other products or services); (i) sales returns and allowances actually paid, granted or accrued on a Licensed Product, including reasonable and customary trade, quantity, prompt pay and cash discounts, and any other similar adjustments, including those granted on account of price adjustments or billing errors, (ii) rejection, recall, return, or wastage replacement of, and for uncollectible amounts on, a Licensed Product or for rebates or retroactive price reductions (including Medicare, Medicaid, copay assistance, managed care, and similar types of rebates and chargebacks), (iii) applicable duties, excise, sale and use taxes or other governmental charges levied on or measured by the billing amount for a Licensed Product, as adjusted for rebates and refunds, including pharmaceutical excise taxes (such as those imposed on a Licensed Product by the United States Patient Protection and Affordable Care Act of 2010 and other comparable laws), and (iv) charges for freight, customs, and insurance related to the distribution of Licensed Products, and wholesaler and distributor administration fees. Net Sales will not be imputed to transfers of Licensed Products as bona fide samples, as donations, for clinical trial purposes, any expanded access program, any compassionate sales or use program (including named patient program or single patient program), or any indigent program. In addition, the sale or transfer of Licensed Products between Licensee and its Affiliates will not result in any Net Sales, with Net Sales to be based only on any subsequent sales or dispositions to a non-Affiliate Third Party.
- 1.13** **"Non-Royalty Sublicense Consideration"** means any consideration received by Licensee from a Sublicensee other than (i) royalties on product sales (royalties on product sales by Sublicensees will be treated as if Licensee made the sale of such product).
- 1.14** **"Patent-Related Expenses"** means costs and expenses (including out-of-pocket attorneys' fees, patent agent fees and governmental filing fees) that the University incurs in prosecuting and maintaining the Licensed Patents.
- 1.15** **"Performance Milestone"** means an act or event specified in Section 9 of the AREPLA and described in Section 5.1 of Terms and Conditions.
- 1.16** **"Period of Applicability"** means the period beginning on the 5th anniversary of the Restatement Date and ending on the earliest to occur of the following: (1) regulatory approval for the first Licensed Product; or (2) the end of the calendar year in which Licensee fails to fund University research for at least one of the individuals identified in Section 3.2.1 in an amount of at least \$350,000 exclusive of indirect costs.
- 1.17** **"Post Termination Period"** means the one-year period following termination of this Agreement, under Section 8 of the Terms and Conditions.
- 1.18** **"Prior Agreement"** means the Exclusive License Agreement between the University and Oxis Biotech, Inc. dated July 18, 2016.
- 1.19** **"Protein Biologic"** shall mean a protein product in the absence of cells, nucleic acid, and virus particles.

- 1.20** “**Sublicense**” when used as a noun, means any agreement between Licensee and a Third Party that contains a grant to University’s Licensed Patents regardless of the name given to the agreement by the parties; when used as a verb, means Licensee’s act of entering into any agreement with a Third Party that contains a grant to University’s Licensed Patents, regardless of the name given to the agreement by the parties.
- 1.21** “**Sublicensee**” means the Third Party in a Sublicense.
- 1.22** “**Territory**” means the geographical area described in Section 3 of the AREPLA.
- 1.23** “**TriKE**” shall mean a trispesific NK cell engager composed of an NK cell binding/activation domain operably linked to an NK cell IL-15 activation domain operably linked to a target cell targeting domain.
- 1.24** “**Third Party**” means any party other than the University or Licensee.
- 1.25** “**University Indemnitees**” means University, its respective regents, officers, employees, students, agents, faculty, representatives, and volunteers.
- 1.26** “**Valid Claim**” means, with respect to a particular country, (a) a claim of any issued and unexpired Licensed Patent in such country whose validity, enforceability, or patentability has not been terminated by any of the following: (i) irretrievable lapse, abandonment, revocation, dedication to the public, or disclaimer; or (ii) a holding, finding, or decision of invalidity, unenforceability, or non-patentability by a court of final jurisdiction, or (b) a claim of a patent application within the Licensed Patents in such country that has not been pending for more than seven years from the earliest filing date to which such claim or the applicable patent application is entitled to claim priority and which claim has not been revoked, cancelled, withdrawn, held invalid, or abandoned.
- 2. TERM.** The term of the AREPLA commences on the Restatement Date as defined in Section 4.1 of the AREPLA and, unless terminated earlier as provided in Section 8, expires on a country-by-country basis upon the expiration of the last to expire Valid Claim within the Licensed Patents in such country (the “Term”).
- 3. GRANT OF LICENSE.**
- 3.1 The Licensee’s Rights.**
- 3.1.1** Licensed Patent. Subject to the terms and conditions of the AREPLA, the University hereby grants to the Licensee an Exclusive license (sub-licensable if Section 7 of the AREPLA is marked “Yes”) under the University’s rights in the Licensed Patent in the Field of Use to make, have made, use, Import, offer to sell and sell Licensed Product in the Territory,
- 3.1.2** Specific Exclusion. University does not grant any other rights under the AREPLA except as contained In Section 3.1.1. Additionally, the University has not agreed to provide Licensee with any assistance under the AREPLA.
- 3.2 Retained Rights, Restrictions, and Development of Additional Applications.**
- 3.2.1 The University’s Retained Rights for Itself.** The University retains an irrevocable, world-wide, royalty-free, non-exclusive right to use the Licensed Technology solely for teaching, research, and educational purposes. For avoidance of doubt, University’s retained right includes use of the Licensed Patents for Corporate Sponsored Research as well as research sponsored by non-profit or governmental entities. The University retains the right to Sublicense its rights under this Section 3.2.1 to one or more non-profit academic or research institutions solely for teaching, research, and educational purposes, provided that such right as to the Restatement Patent Family and the Clec12A Family in the Field of Use excludes use for all Third-Party Corporate Sponsored Research.

3.2.2 Exception for University's Retained Rights for Itself. The retained right in Section 3.2.1 does not include use of the Licensed Patents for Corporate Sponsored Research for a five (5) year period commencing on the Restatement Date for the following employees of the University while they are employed by the University:

Jeff Miller

Martin Felices and

Daniel Vallera

(individually, "**Restricted Individual**"; collectively, "**Restricted Individuals**").

If, during the Period of Applicability, a Corporate Sponsored Research arrangement under the direction of any of the Restricted Individuals results in an invention and if during the Period of Applicability, the rights to such an invention are exclusively licensed to a Third Party ("Triggering Third Party License"), then all of Licensee's prospective payment obligations to the University listed in the AREPLA shall be reduced by 50%, subject to the following:

- (i) The Restricted Individual must actually have manipulated, purposefully sought to modify, or otherwise have used the Licensed Patents to perform the work under the Third-Party Corporate Sponsored Research arrangement.
- (ii) The payment reduction applies prospectively to payments due after the effective date of the Triggering Third Party License.
- (iii) The reduction is not applicable if:
 - (A) University offers the invention to Licensee for an exclusive license on substantially the same terms as in the AREPLA as the Triggering Third Party License, and Licensee rejects the University's offer or fails to respond to the offer within thirty days after having received the University's offer.
 - (B) Licensee accepted a sub-license from the third-party sponsor for the invention.
 - (C) Licensee is not current with its payment or other obligations under the AREPLA.

Following the expiration or termination of the Period of Applicability, the Restricted Individuals are free to conduct any research without any payment reduction.

3.2.3 Right of U.S. Government. The AREPLA is subject to Title 35 Sections 200-204 of the United States Code. Among other things, these provisions provide the United States Government with nonexclusive rights in the Licensed Patent. They also impose the obligation that the Licensed Product sold or produced in the United States be "manufactured substantially in the United States," Licensee will ensure all obligations of these provisions are met.

3.2.4 Transfer of Licensed Products to External Entities. University is free to transfer Licensed Products to the entities described in Sections 3.2.3 and 3.2.4 for the purposes described therein under a material transfer agreement with terms consistent with [NIH Grants Policy Statement](#), including but not limited to Section 8.2.3 (Sharing Research Resources) of the NIH Grants Policy Statement.

3.2.5 Transfer of Licensed Products within the University. University is free to share Licensed Products within the University; provided that University will inform the Restricted Individuals

that for a period beginning on the Restatement Date and concluding at the end of the Period of Applicability, they should notify Licensee if they transfer material(s) that constitute nucleic acid(s) that make the Licensed Product(s) to another investigator at the University, including the name of the recipient investigator. Such notification may be made by email or other written means to an individual or address designated by Licensee. For clarification, the individual researcher receiving such material(s) does not become a Restricted Individual.

3.2.6 Development of Additional Applications. If University notifies Licensee in writing that a Third Party is interested in pursuing a particular application covered by the Licensed Patents in the Field of Use outside of human use (including without limitation canines) ("**Additional Application**"), then Licensee shall inform University (and include sufficient detail) within sixty (60) days after receipt of the notice in writing whether:

- (a) Licensee is already conducting research, development, or commercial activities for such Additional Application, alone or with Third Parties; or
- (b) is actively planning to conduct research, development, or commercial activities for such Additional Application, alone or with Third Parties.

If Licensee informs University in writing that neither (1) nor (2) is applicable, or if Licensee does not respond within the sixty (60) day period, then Licensee will negotiate in good faith with the University regarding granting the right to research, develop and commercialize products for such Additional Application to a Third Party identified by University.

If Licensee informs University in writing that it intends to develop Additional Application, alone or with Third Parties and if at that time, University has technology available to license that it believes would be useful for such development, then Licensee will review such technology and enter good faith discussions to explore possibly licensing the use of the technology for advancing the Additional Application.

4. PATENT PROSECUTION AND MAINTENANCE.

4.1 Review of Licensed Patents. The Licensee acknowledges that it has reviewed each Licensed Patent and that it will not dispute the inventorship, validity, or enforceability of any of the claims made in a Licensed Patent. The Licensee further represents that as of the Restatement Date, it has not and does not manufacture, have manufactured, offer to sell, sell, offer to lease, lease, or import Licensed Products.

4.2 Patent Application Filings during the Term.

4.2.1 Consultation with and Cooperation of Licensee. The University, in consultation with the Licensee, shall determine in which countries Licensed Patents will be filed. The University shall retain counsel of its choice to file and prosecute such Licensed Patents. The University will inform the Licensee of the status of the prosecution of the Licensed Patents, including delivering to the Licensee pertinent notices, written and oral communications with governmental officials, and documents, and shall consult with the Licensee on the prosecution of the Licensed Patents. The Licensee shall cooperate with the University in the filing and prosecution of all Licensed Patents. In furtherance of the foregoing, the Licensee shall notify the University, in writing, of the Individual whom the Licensee has designated to consult and cooperate as provided in this Subsection 4.2.1 and is identified in Section 12 of the AREPLA. Such person shall respond to the University's request for consultation and cooperation on a pending matter within five business days or sooner as may be required under the circumstances. If such person falls to respond in such period, the University, exercising its own judgment and discretion, may respond to the matter as it deems appropriate. Except as provided in Subsection 4.2.2, the Licensee shall reimburse the

University for all Patent-Related Expenses as provided in Section 6.3 and in Section 6 of the AREPLA.

4.2.2 University Retention of Right to File and Prosecute Licensed Patents. No provision of the AREPLA limits, conditions, or otherwise affects the University's right to prosecute a Licensed Patent in any country. The University retains the sole and exclusive right to file or otherwise prosecute a Licensed Patent. In no event shall the Licensee file a patent application with respect to the Licensed Technology. The Licensee shall cooperate with the University in the filing and prosecution of all Licensed Patents.

5. COMMERCIALIZATION.

- 5.1 Commercialization and Performance Milestones.** The Licensee shall use its commercially reasonable efforts, consistent with sound and reasonable business practices and judgment, to commercialize the Licensed Technology and to manufacture and offer to sell and sell Licensed Products as soon as practicable and to maximize sales thereof. The Licensee shall notify University in writing within 30 days after first commercial sale of Licensed Product. The Licensee shall perform or shall cause to happen or be performed all the performance milestones described in Section 9 of the AREPLA.
- 5.2 Covenants Regarding the Manufacture of Licensed Products.** The Licensee hereby covenants and agrees that (i) the manufacture, use, sale, or transfer of Licensed Products shall comply with all applicable federal and state laws, including all federal export laws and regulations; and (ii) the Licensed Products shall not be defective in design or manufacture. The Licensee hereby further covenants and agrees that, pursuant to 35 United States Code Section 204, it shall, and it shall cause each Sublicensee, to substantially manufacture in the United States of America all products embodying or produced through the use of an invention that is subject to the rights of the federal government of the United States of America.
- 5.3 Export and Regulatory Compliance.** The Licensee understands that the Arms Export Control Act (AECA), including its implementing International Traffic in Arms Regulations (ITAR,) and the Export Administration Act (EAA), including its Export Administration Regulations (EAR), are some (but not all) of the laws and regulations that comprise the U.S. export laws and regulations. Licensee further understands that the U.S. export laws and regulations include (but are not limited to): (i) ITAR and EAR product/service/data-specific requirements; (ii) ITAR and EAR ultimate destination-specific requirements; (iii) ITAR and EAR end user-specific requirements; (iv) Foreign Corrupt Practices Act; and (v) antiboycott laws and regulations. The Licensee shall comply with all then-current applicable export laws and regulations of the U.S. Government (and other applicable U.S. laws and regulations) pertaining to the Licensed Products (including any associated products, items, articles, computer software, media, services, technical data, and other information). The Licensee certifies that it shall not, directly or indirectly, export (including any deemed export), nor re-export (including any deemed re-export) the Licensed Products (including any associated products, items, articles, computer software, media, services, technical data, and other information) in violation of U.S. export laws and regulations or other applicable U.S. laws and regulations. The Licensee shall include an appropriate provision in its agreements with its authorized Sublicensees to assure that these parties comply with all then-current applicable U.S. export laws and regulations and other applicable U.S. laws and regulations.
- 5.4 Use of the University's Name and Trademarks or the Names of University Faculty, Staff, or Students.** No provision of the AREPLA grants the Licensee or Sublicensee any right or license to use the name, logo, or any marks owned by or associated with the University or the names, or identities of any member of the faculty, staff, or student body of the University. The Licensee shall not use and shall not permit a Sublicensee to use any such logos, marks, names, or identities without the University's prior written approval.
- 5.5 Governmental Markings and Requirements.**

- 5.5.1 The Licensee shall mark all Licensed Products, where feasible, with patent notice appropriate under Title 35, United States Code, in accordance with Licensee's corporate policies applicable to all Licensee's products.
- 5.5.2 The Licensee is responsible for obtaining all necessary governmental approvals for the development, production, distribution, sale, and use of any Licensed Product, at the Licensee's expense, including, without limitation, any safety studies. The Licensee is responsible for including with the Licensed Product any warning labels, packaging, and instructions as to the use and the quality control for any Licensed Product.
- 5.5.3 The Licensee agrees to register the AREPLA with any foreign governmental agency that requires such registration, and the Licensee shall pay all costs and legal fees in connection with such registration. The Licensee shall comply with all foreign laws affecting the AREPLA or the sale of Licensed Products.
- 5.5.4 Licensee shall comply upon reasonable notice from University with all governmental requests relevant to the Licensed Patents or Licensed Technology directed to either University or Licensee and provide all information and assistance necessary to comply with the governmental requests.

6. PAYMENTS, REIMBURSEMENTS, REPORTS, AND RECORDS.

- 6.1 **Payments.** The Licensee shall pay all amounts due under the AREPLA by check (payable to the "Regents of the University of Minnesota" and sent to the address specified in Section 12.12), wire transfer, or any other mutually agreed-upon method of payment.
- 6.2 **Interest.** All amounts due under the AREPLA shall bear interest at 12% per annum on the entire unpaid balance computed from the due date until the amount is paid.
- 6.3 **Reimbursement of Patent-Related Expenses.** The Licensee shall pay invoices for Patent-Related Expenses under the AREPLA within thirty (30) days of its receipt of the University's invoice. With respect to each invoice, the University shall use reasonable efforts to specify the date on which the Patent-Related Expense was incurred and the purpose of the expense (including, as applicable, a summary of patent attorney services giving rise to the expense); provided, however, the University is not required to disclose to the Licensee any information that is protected by the University's attorney-client privilege. Patent-Related Expenses incurred as of the Restatement Date are set forth in Section 6 of the AREPLA. The University reserves the right to require that Licensee provide and maintain a reasonable advance deposit with the University or some other form of security to ensure payment of Patent-Related Expenses.
- 6.4 **Royalty Payments/Sales Reports.** Within sixty (60) days after the last day of the second and fourth calendar quarters after first commercial sale of Licensed Product by Licensee or Sublicensee during the Term and in any post termination period as set forth in Section 8., the Licensee shall deliver to the University a written sales report in the form attached hereto as Exhibit B, recounting the number and Net Sales Amount (expressed in U. S. dollars) of all sales, leases, or other dispositions of Licensed Products, whether made by the Licensee or a Sublicensee, during such semi-annual period. The Licensee shall deliver such written report to the University even if the Licensee is not required hereunder to pay to the University a payment for sales, leases, or other dispositions of Licensed Products during the semi-annual period. The Licensee shall deliver along with such sales reports its payment for royalties owed on all Net Sales of Licensed Products by the Licensee and the Sublicensees during such semi-annual period.
- 6.5 **Records Retention and Audit Rights.**
 - 6.5.1 Throughout the Term and the Post-termination Period and for five (5) years thereafter, the Licensee, at its expense, shall keep and maintain and shall cause each Sublicensee and each non-affiliated Third Party that manufactures, sells, leases, or otherwise disposes of Licensed

Products on behalf of the Licensee to keep and maintain complete and accurate records of all sales, leases, and other dispositions of Licensed Products during the Term and the Post-termination Period and all other records related to the AREPLA.

6.5.2 In connection with an audit, the Licensee, upon written request, shall deliver to the University and its representatives true, correct, and complete copies (redacted to delete Sublicensee confidential information) of all documents and materials (including electronic records) reasonably relevant to the Licensee's and Sublicensees' performance of the AREPLA, including, without limitation, all Sublicenses granted.

6.5.3 To determine the Licensee's compliance with the terms of the AREPLA, the University, at its expense (except as set forth in this Subsection 6.5.3), may inspect and audit the Licensee's records referred to in Subsection 6.5.1 at the Licensee's address as set forth in the AREPLA or such other location(s) as the parties mutually agree during the Licensee's normal business hours. The Licensee shall cooperate in the audit, including providing at no cost, commodious space in the Licensee's place of business for the auditor. In no event shall University audit the same reporting period more than once. The Licensee shall reimburse the University for its reasonable out-of-pocket expenses to inspect and audit such records if the University, in accordance with the results of such inspection and audit, determines that the Licensee has underpaid amounts owed to the University by at least 5% in a reporting period. The Licensee shall cause each Sublicensee and each non-affiliated Third Party that manufactures, sells, leases, or otherwise disposes of Licensed Products pursuant to a Sublicense from Licensee to grant the University a right to inspect and audit the Sublicensee's records substantially similar to the rights granted to the University in this Subsection 6.5.3. In connection with, and before the commencement of, an audit, if the Licensee requests in writing to the University, then prior to conducting such audit, the Licensee, the University, and the auditor must enter into a confidentiality agreement on customary terms protecting Licensee's non-public, proprietary information. Consistent with generally accepted auditing standards and the auditor's professional judgment, the auditor may disclose only such information to the University and its agents, counsel, or consultants that is necessary to confirm the accuracy of Licensee's reports furnished, and payments made, under the AREPLA.

6.6 Currency and Checks. All computations and payments made under the AREPLA shall be in United States dollars. To determine the dollar value of transactions conducted in non-United States dollar currencies, the parties shall use the exchange rate for the currency into dollars as reported in the Wall Street Journal as the New York foreign exchange mid-range rate on the last business day of the month in which the transaction occurred,

7. INFRINGEMENT.

7.1 Infringement by a Third Party. If a party learns of substantial, credible evidence that a Third Party is making, using, or selling a product in the Field of Use in the Territory that infringes a Licensed Patent, such party shall promptly notify the other party in writing of the possible infringement and in such notice describe in detail the information suggesting infringement of the Licensed Patent. Licensee shall have the first right to institute an enforcement action against such Third Party, provided, however, that prior to commencing an action to enforce a Licensed Patent, the parties shall enter into good faith negotiations on the desirability of bringing suit, the parties to the action, the selection of counsel, and such other matters as the parties may agree to discuss. No provision of the AREPLA limits, conditions, or otherwise affects a party's statutory and common-law rights to commence an action to enforce a Licensed Patent in any such action, the parties agree to cooperate fully with each other and will use reasonable efforts to permit access to relevant personnel, records, papers, information, samples and specimens during regular business hours; provided that University may not be named (nor is Licensee authorized to name University) as a party in any such action without University's written consent. Any amounts recovered (less amounts actually paid for reasonable attorney's fees and legal expenses) by Licensee in any such action or settlement that constitute compensation for lost profits or sales will be considered subject to the royalty rate in Subsection 11.4 of the AREPLA. All other amounts recovered (less amounts actually paid for reasonable attorney's

fees and legal expenses) by Licensee In such action or settlement shall be considered subject to the rate for Non-Royalty Sublicense Consideration in Subsection 11.6 of the AREPLA. In case of third party infringement in a jurisdiction or under circumstances where University must be named a party plaintiff in order for Licensee to bring or maintain an enforcement action, if University does not consent to being named a party plaintiff pursuant to this Section 7.1 after Licensee and University have concluded the good faith discussions described above, and the court in that jurisdiction does not allow Licensee's action to proceed for that reason, then Licensee's payment obligations to University on account of the development and commercialization of Licensed Products covered or claimed by the patent(s) at issue shall be reduced by fifty percent (50%) for Net Sales in that jurisdiction.

- 7.2 Infringement by Licensee.** If any suit, action, or proceeding is brought or commenced against the Licensee alleging the infringement of a patent or other intellectual property right owned by a Third Party by reason of the manufacture, use or sale of Licensed Products, the Licensee shall give the University prompt notice thereof. If the validity of a Licensed Patent is questioned in such suit, action or proceeding, the Licensee shall have no right to make any settlement or compromise which affects the scope, validity, enforceability or otherwise the Licensed Patent without the University's prior written approval.

8. TERMINATION.

- 8.1 University's Right to Terminate for Breach.** Subject to Section 8.2, University may terminate the AREPLA if Licensee:

- 8.1.1** is delinquent on any report or payment.
- 8.1.2** is not diligently developing and commercializing Licensed Product.
- 8.1.3** misses a milestone under Section 9 of the AREPLA.
- 8.1.4** is in material breach of any provision of the AREPLA.
- 8.1.5** provides any false report.
- 8.1.6** fails to enter into a sponsored research agreement within 90 days of the Restatement Date with the University to carry out further research on (1) the TriKE platform including the cytokine linker and the best target antigens on cancer targets and (2) building on higher production systems that generate higher concentrations of TriKEs for expanded use beyond the initial bacterial production used for phase I testing.

- 8.2 University Notification to Licensee of Breach.** To terminate for breach, University must provide Licensee written notice of the breach, and describe such alleged breach in reasonable detail to allow Licensee to determine if a material breach has occurred and the necessary measures to cure. Termination will take effect 30 days after such written notice by University provided, however, that Licensee may extend such notice period by up to thirty (30) additional days upon its written certification that (i) such breach is not reasonably capable of being cured within such 30-day period and (ii) it has commenced and is diligently pursuing efforts to cure such breach.

- 8.3 Licensee's Right to Terminate.** Licensee may terminate the AREPLA:

- 8.3.1** At any time prior to the dosing of the first patient in a Phase I clinical trial for Licensed Product upon payment of \$200,000 to the University; or
- 8.3.2** at any time after the dosing of the first patient in a Phase I clinical trial for Licensed Product upon payment of \$75,000 to the University.

8.3.3 at any time for University's material breach of the AREPLA. Termination under this Section 8.3.3 will take effect 30 days after written notice by Licensee (or such longer time if the breach is not capable of being cured during such 30-day period) unless University remedies the default during such period. Such termination shall be without payment obligation to University, and without prejudice to any other rights Licensee may have against University at law or in equity.

8.4 Either Party's Right to Terminate. The Agreement may be terminated by written notice effective immediately by a Party upon the occurrence of any of the following with respect the other Party: (a) such other Party becomes insolvent, is dissolved or liquidated; (b) voluntary or involuntary proceedings by or against such other Party are instituted in bankruptcy or under any insolvency law, which proceedings, (i) if involuntary, shall not have been dismissed within ninety (90) days after the date of filing, and (ii) if voluntary, shall not have been instituted under Chapter 11 of the United States Bankruptcy Code, 11 U.S.C. §101 et seq.; (c) a receiver or custodian is appointed for such other Party, or proceedings are instituted by or against such other Party for the dissolution of such other Party, which proceedings, if involuntary, shall not have been dismissed within ninety (90) days after the date of filing; or (d) such other Party makes an assignment of substantially all of its assets for the benefit of its creditors, or substantially all of the assets of such other Party are seized or attached and not released within ninety (90) days thereafter .

8.5 Effect of Termination. Upon termination:

8.5.1 The grant of rights under Section 3.1 of the General Terms terminates. Licensee and its Sublicensees may, however, sell or dispose of Licensed Products manufactured prior to termination for the Post Termination Period; and

8.5.2 Upon request, University may grant a license to Sublicensees on financial terms substantially similar to such terms in Sublicense if Sublicensee has performed when due all of its obligations under the Sublicense.

8.5.3 Sublicenses granted by Licensee shall be assigned to University upon request and at University's approval provided that University's obligations under such Sublicense shall be consistent with and not exceed University's obligations to Licensee under the AREPLA and provided that such Sublicensee agrees in a writing sent to University to assume all obligations of the AREPLA for the benefit of University, including the obligations to make all payments and provide all reports due under the AREPLA.

8.5.4 The following survive:

- (a) Licensee's obligation to pay royalties accrued or accruable as of the date of termination.
- (b) Any claim of Licensee or University, accrued or to accrue as of the date of termination, because of any breach or default by the other party; and
- (c) The provisions of Articles 9, 10, 11 and 12, and any other provision that by its nature is intended to survive.

9. INDEMNIFICATION AND INSURANCE.

9.1 Indemnification. Licensee shall indemnify, hold harmless, and defend (and shall require all Sublicensees to indemnify, hold harmless and defend) all University Indemnitees against any third-party claim of any kind arising out of or related to the exercise of any rights granted Licensee under the AREPLA or the breach of the AREPLA by Licensee, except to the extent such third-party claim resulted from University's breach of the AREPLA.

9.2 Insurance.

9.2.1 Throughout the Term, or during such other period as the parties agree in writing, the Licensee shall maintain, and shall cause each Sublicensee to maintain, in full force and effect comprehensive general liability ("CGL") insurance, with single claim limits acceptable to the University. Such insurance policy shall include coverage for claims that may be asserted by the University against the Licensee under Section 9.1 and for claims by a Third Party against the Licensee or the University arising out of the purchase or use of a Licensed Product. Such insurance policy must (i) name the University as an additional insured if the University so requests in writing and (ii) require the insurer to deliver written notice to the University at the address set forth in Section 12.12, at least thirty (30) days before the termination of the policy. Upon receipt of the University's written request, the licensee shall deliver to the University a copy of the certificate of insurance for such policy,

9.2.2 The provisions of Subsection 9.1.1 do not apply if the University agrees in writing to accept the Licensee's or a Sublicensee's self-insurance plan as adequate insurance.

10. REPRESENTATIONS AND WARRANTIES

10.1 Each Party represents and warrants that neither it nor any of its or its Affiliates' employees or agents performing under this Agreement has ever been, or is currently: (a) debarred under 21 U.S.C. § 335a or by any Regulatory Authority; (b) excluded, debarred, suspended, or otherwise ineligible to participate in federal health care programs or in federal procurement or non-procurement programs; (c) listed on the FDA's Disqualified and Restricted Lists for clinical investigators; or (d) convicted of a criminal offense that falls within the scope of 42 U.S.C. § 1320a-7(a), but has not yet been excluded, debarred, suspended, or otherwise declared ineligible. Each Party further covenants that if, during the Term of this Agreement, it becomes aware that it or any of its or its Affiliates' employees or agents performing under this Agreement is the subject of any investigation or proceeding that could lead to that Party becoming a debarred entity or individual, an excluded entity or individual or a convicted entity or individual, in each case pursuant to subsections (a) through (d) of this Section 10.1, such Party will promptly notify the other Party. Each Party further covenants that if, during the Term of this Agreement, it becomes aware that it or any of its or its Affiliates' employees or agents is the subject of any investigation or proceeding that could lead to that entity becoming a debarred entity or individual, an excluded entity or individual or a convicted entity or individual, in each case pursuant to subsections (a) through (d) of this Section 10.1, Licensee will promptly notify University in writing.

10.2 DISCLAIMER OF WARRANTIES. EXCEPT AS OTHERWISE STATED IN ARTICLE 10, UNIVERSITY PROVIDES LICENSEE THE RIGHTS GRANTED IN THE AREPLA AS IS AND WITH ALL FAULTS, UNIVERSITY MAKES NO REPRESENTATIONS AND EXTENDS NO WARRANTIES OF ANY KIND, EITHER EXPRESS OR IMPLIED. AMONG OTHER THINGS, THE UNIVERSITY EXPRESSLY DISCLAIMS ANY WARRANTIES CONCERNING AND MAKES NO REPRESENTATIONS:

10.3 that the Legacy Patent Applications or Restatement Patent Applications will be allowed or granted or that a patent will issue from any patent application.

10.4 concerning the validity, enforceability, interpretation of claims or scope of any Licensed Patent.

10.5 that the exercise of the rights or licenses granted to the Licensee under the AREPLA will not infringe a Third Party's patent or violate its intellectual property rights.

10.6 that the exploitation of Licensed Patents or Licensed Technology will be successful.

The Licensee shall cause each Sublicensee to give the University warranties and disclaimers and exclusions of warranties substantially similar to the warranty and disclaimers and exclusions of warranties in favor of the University in this Section 10.

11. DAMAGES. Neither party shall be liable to the other party for any special, consequential, lost profit, expectation, punitive or other indirect damages in connection with any claim arising out of or related to the

AREPLA. Except for party's gross negligence or wilful misconduct, and except for a breach of Section 12.1.2 involving information received from a third party, in no event shall a party's liability to the other party exceed the payments made to University by Licensee during the twelve (12) months prior to the event that gave rise to the claim. University will accept liability for a breach of Section 12.1.2 to the extent caused by the negligent acts or omissions of a University employee acting within the scope of their employment capped by the limit set forth in Minnesota Statutes Section 3.736, Subdivision 4.

12. GENERAL TERMS

12.1 Access to University Information.

12.1.1 Data Practices Act. The parties acknowledge that the University is subject to the terms and provisions of the Minnesota Government Data Practices Act, Minnesota Statutes §13.01 et seq, ("Act"), and that the Act requires, with certain exceptions, the University to permit the public to inspect and copy any information that the University collects, creates, receives, maintains, or disseminates.

12.1.2 Confidentiality. To the extent permitted by law, including as provided in the Act, the University shall hold in confidence and disclose only to University employees, agents and contractors who need to know the reports described in Section 10 of the AREPLA and in Section 6.4 and the records inspected in accordance with Section 6.5 of the Terms and Conditions. No provision of the AREPLA is to be construed to further prohibit, limit, or condition the University's right to use and disclose any information in connection with enforcing the AREPLA, in court or elsewhere.

12.2 Amendment and Waiver. The AREPLA may be amended from time to time only by a written instrument signed by the parties. No term or provision of the AREPLA may be waived and no breach excused unless such waiver or consent is in writing and signed by the party claimed to have waived or consented. No waiver of a breach is to be deemed a waiver of a different or subsequent breach.

12.3 Applicable Law and Forum Selection. The internal laws of the state of Minnesota, without giving effect to its conflict of laws principles, govern the validity, construction, and enforceability of the AREPLA. A suit, claim, or other action to enforce the terms of the AREPLA may be brought only in the state courts of Hennepin County, Minnesota. The Licensee hereby submits to the Jurisdiction of that court and waives any objections it may have to that court asserting jurisdiction over the Licensee or its assets and property.

12.4 Assignment and Sublicense. Except as permitted under Subsection 3.1.1 and Section 12.5, the Licensee shall not assign or sublicense its interest or delegate its duties under the AREPLA. Any assignment, sublicense, or delegation attempted to be made in violation of this section is void. Absent the consent of all the parties, an assignment or delegation will not release the assigning or delegating party from its obligations. The AREPLA inures to the benefit of the Licensee and the University and their respective permitted sublicensees and trustees.

12.5 Change of Control. Licensee may assign the AREPLA as part of a Change of Control upon prior and complete performance of the following conditions:

12.5.1 Licensee must give University 30 days prior written notice of the assignment, including the new assignee's contact information.

12.5.2 the new assignee must agree in writing to University to be bound by the AREPLA.

12.5.3 University must have received the full Change of Control Fee.

12.6 Consent and Approvals. Except as otherwise expressly provided, in order to be effective, all consents or approvals required under the AREPLA must be in writing.

- 12.7 Construction.** The headings preceding and labelling the sections of the AREPLA are for the purpose of identification only and are not to be employed or used for the purpose of construction or interpretation of any portion of the AREPLA. As used herein and where necessary, the singular includes the plural and vice versa, and masculine, feminine, and neuter expressions are interchangeable.
- 12.8 Enforceability.** If a court of competent Jurisdiction adjudges a provision of the AREPLA to be unenforceable, invalid, or void, such determination is not to be construed as impairing the enforceability of any of the remaining provisions hereof and such provisions will remain in full force and effect.
- 12.9 Entire Agreement.** The parties intend the AREPLA (including all attachments, exhibits, and amendments hereto) to be the final and binding expression of their contract and agreement and the complete and exclusive statement of the terms thereof. The AREPLA cancels, supersedes, and revokes all prior negotiations, representations, and agreements among the parties, whether oral or written, relating to the subject matter of the AREPLA.
- 12.10 Language and Currency.** Unless otherwise expressly provided in the AREPLA and to be effective, all notices, reports, and other documents and instruments that a party elects or is required to deliver to the other party must be in English, and all notices, reports, and other documents and instruments detailing revenues and earned under the AREPLA or expenses chargeable to a party must be United States dollar denominated.
- 12.11 No Third-Party Beneficiaries.** No provision of the AREPLA, express or implied, is intended to confer upon any person other than the parties to the AREPLA any rights, remedies, obligations, or liabilities hereunder. No Sublicensee may enforce or seek damages under the AREPLA.
- 12.12 Notices.** In order to be effective, all notices, requests, and other communications that a party is required or elects to deliver must be in writing and must be delivered personally, or by facsimile or electronic mail (provided such delivery is confirmed), or by a recognized overnight courier service or by United States mail, first-class, certified or registered, postage prepaid, return receipt requested, to the other party at its address set forth below or to such other address as such party may designate by notice given under this Section 12.12:

If to the University: University of Minnesota
Office for Technology Commercialization
200 Oak Street, SE Suite 280
Minneapolis, MN 55455
Phone: 612.624.0550
Fax: 612.624.6554
E-mail: otcagree@umn.edu

For notices sent under Section 8, with a copy to:

University of Minnesota Office of the General Counsel
Transactional Law Services
350 McNamara Alumni Center
200 Oak Street S.E. Minneapolis, MN 55455-2006
Facsimile No.: 612.626.9624
E-mail: contracts@mail.ogc.umn.edu

If to the Licensee: As indicated in Section 12 of the AREPLA.

- 12.13 Relationship of Parties.** In entering into, and performing their duties under the AREPLA, the parties are acting as independent contractors and independent employers. No provision of the AREPLA

creates or is to be construed as creating a partnership, joint venture, or agency relationship between the parties. No party has the authority to act for or bind the other party in any respect.

12.14 Security Interest. In no event may the Licensee grant, or permit any person to assert or perfect, a security interest in the Licensee's rights under the AREPLA.

Exhibit B**Restatement Patent Family**

Patent Application #	University case No.	Territory	Application Date	Status	Title
62/906,660	2020-115	USA	09/26/2019	Expired	HIV Targeting TriKE Molecules
17/762,354	2020-115	USA	03/21/2022	Pending	HIV targeting TriKE molecules
PCT/US2020/052671	2020-115	PCT	09/25/2020	Expired	HIV targeting TriKE molecules
2020354654	2020-115	Australia	09/25/2020	Pending	HIV Targeting TriKE Molecules
2022/03627	2020-115	South Africa	09/25/2020	Pending	HIV Targeting TriKE Molecules
10-2022-7011781	2020-115	South Korea	09/25/2020	Pending	HIV Targeting TriKE Molecules
2022-519141	2020-115	Japan	09/25/2020	Pending	HIV Targeting TriKE Molecules
202217024399	2020-115	India	09/25/2020	Pending	HIV Targeting TriKE Molecules
291646	2020-115	Israel	09/25/2020	Pending	HIV Targeting TriKE Molecules
20870067.4	2020-115	EPO	09/25/2020	Pending	HIV Targeting TriKE Molecules
2020800678687	2020-115	China	09/25/2020	Pending	HIV Targeting TriKE Molecules
3,151,281	2020-115	Canada	09/25/2020	Pending	HIV Targeting TriKE Molecules
112022005666-4	2020-115	Brazil	09/25/2020	Pending	HIV Targeting TriKE Molecules
62023067880.2	2020-115	Hong Kong	09/25/2020	Pending	HIV Targeting TriKE Molecules
62/901,198	2020-079	USA	09/16/2019	Expired	HER2 TriKEs for Cancer Therapy
PCT/US2020/050851	2020-079	PCT	09/15/2020	Expired	HER2 TriKEs for Cancer Therapy
20864423.7	2020-079	EPO	09/15/2020	Pending	HER2 TriKEs for Cancer Therapy
62023067248.2	2020-079	Hong Kong	09/15/2020	Pending	HER2 TriKEs for Cancer Therapy
BR112022004712-6	2020-079	Brazil	09/15/2020	Pending	HER2 TriKEs for Cancer Therapy
10-2022-7012588	2020-079	South Korea	09/15/2020	Pending	HER2 TriKEs for Cancer Therapy
202217021580	2020-079	India	09/15/2020	Pending	HER2 TriKEs for Cancer Therapy
2022-517139	2020-079	Japan	09/15/2020	Pending	HER2 TriKEs for Cancer Therapy
291343	2020-079	Israel	09/15/2020	Pending	HER2 TriKEs for Cancer Therapy
202080079445.7	2020-079	China	09/15/2020	Pending	HER2 TriKEs for Cancer Therapy
3,154,158	2020-079	Canada	09/15/2020	Pending	HER2 TriKEs for Cancer Therapy

Patent Application #	University case No.	Territory	Application Date	Status	Title
2020350524	2020-079	Australia	09/15/2020	Pending	HER2 TriKEs for Cancer Therapy
17/641,594	2019-079	United States	3/9/2022	Pending	HER2 TriKEs for Cancer Therapy
62/747,983	2019-050	United States	10/19/2018	Expired	CLEC12A Targeting Tri-specific Killer Engager (TriKE) for Targeting of Myeloid Malignancies
PCT/US2019/056777	2020-050	World	10.17.2019	Expired	CLEC12A Targeting Tri-specific Killer Engager (TriKE) for Targeting of Myeloid Malignancies
2019361096	2019-050	Australia	10.17.2019	Pending	CLEC12A Targeting Tri-specific Killer Engager (TriKE) for Targeting of Myeloid Malignancies
10-2021-7011728	2019-050	South Korea	10.17.2019	Pending	CLEC12A Targeting Tri-specific Killer Engager (TriKE) for Targeting of Myeloid Malignancies
2021521098	2019-050	Japan	10.17.2019	Pending	CLEC12A Targeting Tri-specific Killer Engager (TriKE) for Targeting of Myeloid Malignancies
202117022002	2019-050	India	10.17.2019	Pending	CLEC12A Targeting Tri-specific Killer Engager (TriKE) for Targeting of Myeloid Malignancies
282193	2019-050	Israel	10.17.2019	Pending	CLEC12A Targeting Tri-specific Killer Engager (TriKE) for Targeting of Myeloid Malignancies
19873982.3	2019-050	EPO	10.17.2019	Pending	CLEC12A Targeting Tri-specific Killer Engager (TriKE) for Targeting of Myeloid Malignancies
62022047273.7	2019-050	HK	10.17.2019	Pending	CLEC12A Targeting Tri-specific Killer Engager (TriKE) for Targeting of Myeloid Malignancies
2019800675953	2019-050	China	10.17.2019	Pending	CLEC12A Targeting Tri-specific Killer Engager (TriKE) for Targeting of Myeloid Malignancies
3,114,707	2019-050	Canada	10.17.2019	Pending	CLEC12A Targeting Tri-specific Killer Engager (TriKE) for Targeting of Myeloid Malignancies
17/285,447	2019-050	United States	4.14.2021	Pending	CLEC12A Targeting Tri-specific Killer Engager (TriKE) for Targeting of Myeloid Malignancies
2021113936	2019-050	Russia	10.17.2019	Pending	CLEC12A Targeting Tri-specific Killer Engager (TriKE) for Targeting of Myeloid Malignancies

Exhibit C
Clec12A Family

Patent application #	UMN case #	Territories	Application Filing date	Status	Title
62/916,340	2020-111	United States	10/17/2019	Expired	CLEC12A Targeting Single-Domain Antibody Sequences for Immunotherapeutic Use
PCT/US2020/055468	2020-111	World	10.14.2020	Expired	CLEC12A Targeting Single-Domain Antibody Sequences for Immunotherapeutic Use
2020368354	2020-111	Australia	10.14.2020	Pending	CLEC12A Targeting Single-Domain Antibody Sequences for Immunotherapeutic Use
10-2022-7016032	2020-111	South Korea	10.14.2020	Pending	CLEC12A Targeting Single-Domain Antibody Sequences for Immunotherapeutic Use
2022-522867	2020-111	Japan	10.14.2020	Pending	CLEC12A Targeting Single-Domain Antibody Sequences for Immunotherapeutic Use
202217025701	2020-111	India	10.14.2020	Pending	CLEC12A Targeting Single-Domain Antibody Sequences for Immunotherapeutic Use
292238	2020-111	Israel	10.14.2020	Pending	CLEC12A Targeting Single-Domain Antibody Sequences for Immunotherapeutic Use
20877981.9	2020-111	EPO	10.14.2020	Pending	CLEC12A Targeting Single-Domain Antibody Sequences for Immunotherapeutic Use
62023067717.6	2020-111	HK	10.14.2020	Pending	CLEC12A Targeting Single-Domain Antibody Sequences for Immunotherapeutic Use
202080087719.7	2020-111	China	10.14.2020	Pending	CLEC12A Targeting Single-Domain Antibody Sequences for Immunotherapeutic Use
3158111	2020-111	Canada	10.14.2020	Pending	CLEC12A Targeting Single-Domain Antibody Sequences for Immunotherapeutic Use
BR112022007219-8	2020-111	Brazil	10.14.2020	Pending	CLEC12A Targeting Single-Domain Antibody Sequences for Immunotherapeutic Use
17/768,793	2020-111	United States	4.13.2022	Pending	CLEC12A Targeting Single-Domain Antibody Sequences for Immunotherapeutic Use

SPONSORED RESEARCH AGREEMENT

THIS AGREEMENT is entered into effective as of July 1, 2023 (the “Effective Date”) by and between Regents of the University of Minnesota (the “University”), a public educational institution and a Minnesota constitutional corporation, and GT Biopharma, Inc. (the “Sponsor”), a Delaware Corporation. This Agreement is entered into by the University through its Office of Sponsored Projects Administration.

Purpose

The research program contemplated by this Agreement is of mutual interest and benefit to University and to Sponsor and will further the instructional and research objectives of the University. The research is to be funded by Sponsor and carried out by the University.

NOW, THEREFORE, the parties agree as follows.

Article 1 – Term

The Term of this Agreement shall commence on the Effective Date and unless earlier terminated as provided in Article 9 shall expire on later of the delivery of the final report, or payment of the final installment pursuant to Section 4.2 hereof (“Expiration Date”). The parties may extend the term of this Agreement for additional periods with or without additional funding through duly executed amendments.

Article 2- Research Work

- 2.1 University shall perform the project as set forth in Appendix 1 (the “Project”) in accordance with the terms and conditions of this Agreement. Anything in this Agreement to the contrary notwithstanding, Sponsor and University may at any time amend Project by mutual written agreement. Any budgetary information included in the attachments to this agreement is for informational purposes only; the University retains the right to re-budget funds within the funded amount as needed to further project objectives.
- 2.2 The Project shall be under the direction of Jeffrey Miller, MD (“Principal Investigator”). In the event that the Principal Investigator (and/or his sub-investigator Dr. Martin Felices) becomes unable or unwilling to continue Project, and a mutually acceptable substitute is not available, University and/or Sponsor shall have the option to terminate said Project in accordance with Article 9. This Agreement does not limit the freedom of individuals participating in this Project to engage in any other research.

Article 3 - Reports and Conferences

- 3.1 Written progress reports shall be provided by University to Sponsor yearly (or such other frequency that Sponsor and Principal Investigator may agree from time to time), or upon
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completion of each phase of the Project as detailed in Appendix 1, whichever is the earlier. A final report shall be submitted by University within ninety (90) days of the conclusion or early termination of this Agreement. All progress reports shall include a high level summary of current expenditures against the agreed-upon budget for the Research Project.

- 3.2 During the term of this Agreement, representatives of University will meet with representatives of Sponsor at times and places mutually agreed upon to discuss the progress and results, as well as ongoing plans or changes.

Article 4 - Costs, Billings, and Other Support

- 4.1 University shall use reasonable efforts to complete the Project for a fixed sum of One Million Seven Hundred Twenty-Four Thousand Six Hundred Eighty-Six dollars (\$1,724,686) ("Contract Price"), which Contract Price shall be paid in seven (7) installments as set forth in Section 4.2 below. The Contract Price does not include any fees payable under Section 8.5.

- 4.2 Sponsor agrees to make an initial payment of Four Hundred Fifty Thousand dollars (\$450,000.00) upon receipt of an invoice from University. Such initial invoice will be sent within thirty (30) days of execution of the Agreement. Sponsor agrees to make a second payment in the amount of One Hundred Ninety Six Thousand Seven Hundred Fifty-Seven dollars and Twenty-Five cents (\$196,757.25) on April 1, 2024. Sponsor then agrees to make four (4) additional quarterly payments (on July 1, 2024, October 1, 2024, January 2, 2025, and April 1, 2025) in the amount of Two Hundred Fifteen Thousand Five Hundred Eighty-Five dollars and Seventy-Five cents (\$215,585.75), following receipt of an invoice from the University. Sponsor shall make a final payment of Two Hundred Fifteen Thousand Five Hundred Eighty-Five dollars and Seventy-Five cents (\$215,585.75) on the earlier of thirty (30) days after receipt of the final report, or July 1, 2025.

Any fees payable under Section 8.5 will be invoiced separately in accordance with Section 8.5.

- 4.3 University shall acquire title upon acquisition of any equipment purchased or fabricated with funds provided by Sponsor under this Agreement. Sponsor shall provide the following equipment to University under the following conditions:

[Either (a) indicate "none" or (b) insert a list of equipment to be provided, indicate loan or gift, and attach a signed copy of equipment loan(s) or deed(s) of gift:]

NONE.

- 4.4 Payments made under this agreement shall be in United States dollars and shall be made payable to "Regents of the University of Minnesota". All payments shall be accompanied by the University invoice number, the Contract number, and name of Principal Investigator. Payments shall be sent to:

Regents of the University of Minnesota
NW 5957
P.O. Box 1450
Minneapolis, MN 55485-5957
Ph: 612.624.4313
Fax: 612.626.0321

Article 5 – Nondisclosure

- 5.1 For purposes of this Agreement, “Confidential Information” means written or tangible information disclosed by either party to the other, which at the time of disclosure is clearly and conspicuously labeled “Confidential” or “Proprietary”. Confidential Information shall also include oral and visual disclosures which are identified as confidential at the time of such disclosures and which are confirmed and summarized within fifteen (15) days of the disclosure by the disclosing party in a writing that sets forth the substance of the Confidential Information disclosed. The parties agree to maintain confidentiality of the Confidential Information during the term of this Agreement, including any renewal periods, and for a period of three (3) years from the effective termination or expiration date of this Agreement. Neither party shall use said Confidential Information for any purpose other than those purposes specified in this Agreement. The parties may disclose Confidential Information to employees requiring access thereto for the purposes of this Agreement provided, however, that prior to making any such disclosures each such employee shall be apprised of the duty and obligation to maintain Confidential Information in confidence and not to use such information for any purpose other than in accordance with the terms and conditions of this Agreement. Neither party will be held financially liable for any inadvertent disclosure, but each will agree to use its reasonable efforts not to disclose any Confidential Information. For the avoidance of doubt, reports, results and data generated under this Agreement are not University Confidential Information.
- 5.2 Nothing contained herein will in any way restrict or impair either party's right to use, disclose, or otherwise deal with any Confidential Information which:
- 5.2.1 At the time of its receipt, is generally available in the public domain, or thereafter becomes available to the public through no act of the receiving party;
 - 5.2.2 Was independently known prior to receipt thereof, or made available to such receiving party as a matter of lawful right by a third party;
 - 5.2.3 Is received without obligation of confidentiality from a third party; or
 - 5.2.4 Is required by law (including the Minnesota Government Data Practices Act), and/or regulation or court order to be disclosed. In the event that Confidential Information is required to be disclosed pursuant to this subsection, the party required to make disclosure shall notify the other to allow that party to assert whatever exclusions or
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exemptions may be available to it under law.

5.3 Export Controls:

- 5.3.1 The parties acknowledge that they must comply with export control laws, including the International Traffic in Arms Regulations (ITAR), 22 C.F.R. pts. 120-130; the Export Administration Regulations (EAR), 15 C.F.R. pts. 730-774; and the Foreign Assets Control Regulations, 31 C.F.R. pts. 501-598.
- 5.3.2 Notwithstanding any other term herein, the University's research in connection with this Agreement shall constitute "fundamental research" for purposes of export control laws. University-generated technical data and software that arise during or result from "fundamental research" are not subject to the ITAR or EAR.
- 5.3.3 The Sponsor shall not convey technical data, technology, commodities, or software on the U.S. Munitions List, 22 C.F.R. pt. 121, or the Commerce Control List, 15 C.F.R. pt. 774, to the University without the prior written consent of the University's Export Controls Officer (J. Patrick Briscoe, bris0022@umn.edu, 612-625-3860). The University may decline receipt of listed items at its sole discretion and at no penalty.

Article 6 - Publicity

- 6.1 Subject to Section 6.3 below, Sponsor will not use the name, logos and other marks and trade names of University, nor of any member of University's Project staff, in any written publicity, advertising, or promotional material, news release, or other form of public written statement related to this Agreement or to the Project, without the prior written approval of an authorized representative of University, provided, that Sponsor may in any written materials disclose that the research under this Agreement is conducted in the laboratories of the Principal Investigator and his sub-investigator. Subject to Section 6.2 below, University will not use the name, logos and other marks and trade names of Sponsor, nor any employee of Sponsor, in any publicity without the prior written approval of Sponsor. For clarity, disclosures made pursuant to binding confidentiality agreements shall not be deemed public statements under this Article 6; provided that in any disclosures made pursuant to such binding confidentiality agreements, Sponsor shall expressly state that the disclosures have not been reviewed, approved, or endorsed by the University
 - 6.2 Pursuant to the University's Openness in Research Policy (a copy of which may be found at http://www1.umn.edu/regents/policies/academic/Openness_in_Research.pdf) the University shall be allowed to disclose the following non-confidential information without the approval of the Sponsor: (1) the existence of the contract or grant; (2) the identity of the Sponsor or the grantor and, if a subcontract is involved, the identity of the prime contractor if the results of the research must be reported to the sponsor, grantor, or prime contractor; and (3) the purpose and the scope of the proposed research. The University
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may also disclose information as needed to comply with institutional reporting requirements, conflict of interest reviews, or in sponsored projects proposals or award documents (e.g., list of current and pending support.)

- 6.3 In accordance with the rules and regulations of the U.S. Securities Exchange Commission ("SEC") and other reporting requirements for publicly listed companies, Sponsor may disclose the following non-confidential information without the approval of the University: (1) the existence of the contract; (2) the identity of the University, the Principal Investigator and his sub-investigator and, if a subcontract is involved, the identity of the prime contractor; and (3) the purpose and the scope of the proposed research. For clarity, the Sponsor may also disclose such additional information as needed to comply with the SEC or other U.S. government reporting or disclosure requirements or other such reporting or disclosure requirements in accordance with applicable laws governing the parties and research performed under the terms of this Agreement.

Article 7 – Publications

7.1 Sponsor recognizes that under University policy the results of the Project must be publishable and agrees that researchers engaged in the Project shall be permitted to present at symposia, national or regional professional meetings and to publish in journals, theses or dissertations, or otherwise of their own choosing, methods and results of the Project. University shall have the final authority to determine the scope and content of any publication; provided, however, that University shall provide copies of any proposed publication to Sponsor at least thirty (30) days in advance of the publication or presentation of a poster or abstract, and at least forty-five days in advance of the publication or presentation of a full-length paper to review and object to such publication or presentation because such draft either contains information deemed to be Confidential Information under the provisions of Article 5 of this Agreement, or reveals information that if published within such time period days would have an adverse effect on a patent application in which Sponsor owns full or part interest, or intends to obtain an interest from University pursuant to this Agreement. In the event that Sponsor notifies the University in writing that the proposed publication or presentation contains Sponsor's Confidential Information, the University shall remove any Sponsor Confidential Information from the draft prior to such publication or presentation. In the event Sponsor requests in writing a delay in publication to file for patent protection, the University and the Researcher shall refrain from making such publication or presentation for a maximum of ninety (90) days from the receipt of such objection, and Sponsor shall indicate with specificity to what manner and degree University may disclose said information during the ninety (90) day period.

7.2 Publication by either party to this Agreement shall give proper credit to the other party for the cooperative character of the investigation.

7.3 TriKE™ is a trademark of GT Biopharma, Inc. TriKE™ shall appear in all publications by University describing any aspect of the Research, and an acknowledgement of financial support from GT Biopharma, Inc. shall also be included in the acknowledgment section of the publication.

Article 8 – Intellectual Property and License of Inventions

8.1 Use of Research Results.

8.1.1 Reserved.

8.1.2 Except for (a) University's right to control publication of its own research results, (b) patented and patent-pending University Subject Inventions, and (c) University Confidential Information, Sponsor will have the free, irrevocable, non-exclusive unlimited right to use all research results for any purpose worldwide.

8.2 Subject Inventions.

8.2.1 "Subject Invention" means any patentable invention (excluding design patents) that is first conceived or reduced to practice by one or more employees of University, alone or with others, in performance of the Project. The inventorship of a Subject Invention will be determined in accordance with Title 35 of the United States Code. "Subject Invention" does not include copyrightable material, including source code or software.

8.2.2 "University Subject Inventions" are those Subject Inventions invented solely by employees of University. "Joint Subject Inventions" are those Subject Inventions invented by employees of University jointly with employees of Sponsor.

8.2.3 No rights to University background intellectual property are granted under the terms of this agreement except as provided in Section 8.5.

8.3 Patent Applications and Costs

8.3.1 Each party shall promptly disclose to the other party in writing any Subject Invention of which that party becomes aware during the Term or afterwards.

8.3.2 Sponsor, in consultation with University, shall have the right to control the preparation, filing, and prosecution of each patent application that is specific to a Subject Invention. Sponsor shall have six (6) months from receipt of an invention disclosure from University to notify University whether it desires to file a patent application on the Subject Invention ("Subject Invention Review Period"). If Sponsor files a patent application, then Sponsor shall diligently pursue filing of the patent application in the name of University with respect to University Subject Inventions and in the name of both University and Sponsor in the case of Joint Subject Inventions. Although Sponsor shall have the ultimate decision authority in preparation, filing, and prosecution of each patent application that is specific to a Subject Invention, Sponsor shall keep University's office for Technology Commercialization informed (with copy to otcpatent@umn.edu) as to all material

matters relevant to the patent prosecution process and decision matters, and the Sponsor shall give due consideration to any recommendations made by the University concerning the patent prosecution matters. Sponsor and Sponsor's counsel will not contact University inventors regarding drafting and prosecution without first contacting University's office for Technology Commercialization. Without limiting the foregoing, Sponsor or Sponsor's counsel shall provide a copy of the draft application and responses to office actions to University at otcpatent@umn.edu and an opportunity to review and provide comments on such application. Further, Sponsor shall provide, or direct Sponsor's counsel to provide, University with all serial numbers and filing dates, together with copies of all applications and patents that issue therefrom, including copies of all office actions, responses and all other substantive communications to and from the U.S. Patent and Trademark Office and the patent offices in any other jurisdictions. Sponsor shall be responsible for the full expense of Subject Invention patent application and prosecution.

If Sponsor notifies University that the invention disclosure was delivered, such that more research under the research plan set forth in Appendix 1 is required for Sponsor to determine whether a Subject Invention is patentable, or for Sponsor to decide whether to file a patent application on the Subject Invention, then University will provide Sponsor an additional six months (or such longer time mutually agreed to by University and Sponsor for additional research to be conducted) to determine whether the Subject Invention is patentable. For clarity, the foregoing provision does not require the University to conduct additional research not included in the research plan attached hereto as Appendix 1 unless in the exercise of its sole discretion the University agrees to conduct such further research in an amendment to this Agreement.

- 8.3.3 If Sponsor decides (i) not to prepare, file, or prosecute patent applications specific to a Subject Invention within the Subject Invention Review Period, (ii) not to file an application in a particular jurisdiction, (iii) to discontinue prosecution of a pending application or a particular set of claims of a patent application, which set is specific to a Subject Invention, or (iv) not to pay any required fee to maintain a pending patent application or an issued patent, Sponsor shall promptly (but in no event less than 30 days before an action is required) notify University of its decision. In such case, University shall have the right to file, prosecute, and maintain said patent or patent application, or to file an application directed to that abandoned claim set, at its sole discretion and expense without further obligations to the Sponsor, provided, however, that if University intends to offer the right to a third party, to license or otherwise commercialize such patent or patent application, then the University shall notify Sponsor in writing thereof. This obligations expires in 3 years from the date the University receives notice of one of the circumstances described in 8.3.3 (i) through (iv).

- 8.4 Nothing in this Article 8 shall be interpreted in a manner contrary to the publication
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provisions of Article 7 herein.

8.5 **Sponsor's Licensing Options.**

8.5.1 **Option to Foreground IP:** Sponsor is hereby granted an exclusive option to negotiate a license to all Subject Inventions made under this Agreement for which it has filed a patent application as provided in Section 8.3.2. The Parties agree that the terms of such license agreement shall be as set forth on Appendix 3 hereto and incorporated into a form substantially similar to the AREPLA . The option period expires six (6) months after the date Sponsor notified University that it has filed a patent application covering the applicable Subject Invention as provided in Section 8.3.2. The patent rights under this provision apply only to patent rights specific to a Subject Invention for which Sponsor is responsible for filing, prosecution and maintenance of patent protection. If Sponsor declines the option, then Sponsor's rights in the Subject Invention terminate and the University is free to offer the Subject Invention to other parties without any obligation to Sponsor. For clarity, any improvement to the University Background IP (as defined below) that is made in the conduct of this Agreement and that results in a new patent application shall constitute a Subject Invention hereunder and shall be subject to this Section 8.5.1. To the extent that such Subject Invention requires a license to the University's Background IP, such license to the University's Background IP shall be subject to the restrictions applicable to the underlying Background IP set forth below in Section 8.5.2. For clarity, no such restrictions would apply to Subject Inventions that do not require a license to the University's Background IP.

8.5.2 **Option to Background IP.** As further detailed in Aim #3 of the research plan set forth on Appendix 1, the University will use two discrete University owned inventions (HER-2 PACC and HSA-PACC) as described in Tech Comm Case UMN 2024-041 and covered under a US Provisional patent application, number 63/611,290 (referred to individually, "HER-2 PACC" and "HSA-PACC", and collectively as "University Background IP") to increase the pharmacokinetic properties of certain TriKE products exclusively licensed to Sponsor under Agreements A#20170047, A#2021-0831 and "AREPLA" ("University TriKE Proteins"). Depending on the results of Aim # 3 of the Project, Sponsor may wish to obtain rights to University Background IP. Sponsor may obtain such rights in the following manner:

(a) HER-2 PACC. At any time during this Agreement or any extension thereof for continued work with HER-2 PACC, Sponsor may notify University that it wishes to use HER-2 PACC under an exclusive use license for internal research purposes only. The field of use for such internal research license is the use of HER 2 PACC in combination with IL-15 containing proteins (including TriKEs) but with no other limitations other than those previously agreed to in the agreements governing Sponsor's rights to the University TriKE Proteins. Upon such notification and payment of a one-time fee of \$10,000, the

University will grant and hereby grants to Sponsor such license for a period of 5 years from the date of Sponsor's notification. For clarity, during the term of such license, the University shall not grant to any third party a commercial license to the applicable University Background IP – i.e., HER-2 PACC in combination with IL-15 containing proteins (including TriKEs).

At any time during the term of the SRA or any extension thereof involving HER-2 PACCs, or the term of the 5-year internal research license above, Sponsor may notify University that it wishes to convert such option or such internal research use license to a royalty bearing commercial license under the terms set forth in Appendix 3. Upon receipt of such notification, the University and Sponsor will enter into a royalty bearing commercial license consistent with the terms of Appendix 3 and incorporated into a form substantially similar to the AREPLA.

- (b) HSA-PACC In Combination with University TriKE Proteins. At any time during this Agreement or any extension thereof for continued work with HSA-PACC Sponsor may notify University that it wishes to use HSA-PACC in combination with University TriKE Proteins under an exclusive use license for internal research purposes only. Upon such notification and payment of a one-time fee of \$10,000, the University will grant and hereby grants such license for a period of 5 years from the date of Sponsor's notification. The field of use for such non-exclusive internal research license is the use of HSA-PACC in combination with University TriKE Proteins. For clarity, during the term of such license, the University shall not grant to any third party a commercial license to the applicable University Background IP– i.e., HSA-PACC in combination with University TriKE Proteins.

At any time during the term of the SRA or any extension thereof involving HSA PACCs, or the term of the 5-year internal research license above, Sponsor may notify University that it wishes to convert such option or such internal research use license to a royalty bearing commercial license under the terms set forth in Appendix 3. Upon receipt of such notification, the University and Sponsor will enter into a royalty bearing commercial license consistent with the terms of Appendix 3 and incorporated into a form substantially similar to the AREPLA.

- (c) HSA-PACC In Combination With IL-15 Containing Proteins. At any time during this Agreement or any extension thereof for continued work with HSA-PACC, Sponsor may notify University that it wishes to commercially license HSA-PACC in combination with IL-15 containing proteins (other than TriKEs). The terms of such license will be those set forth on Appendix 3. Unless otherwise agreed to by the University, such license will be licensed for human use only, and solely for delivery as a protein therapeutics.
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By way of example and without limitation of any kind, below is a non-exhaustive list of fields of use that are NOT granted for use of HSA-PACC under Section 8.5.2(c):

1. Non-human therapeutic uses
2. Delivery or administration of HSA-PACC through a cell based method (e.g., T cells, NK cells, Myeloid cells, etc.)
3. Delivery or administration of HSA-PACC through a nucleic acid-based method
4. Delivery or administration of HSA-PACC through a virus-based method
5. Delivery or administration of HSA-PACC through any method other than as a stand-alone protein introduced directly into the human body (e.g., injection or saline infusion)

For clarity, Licensee may use cell-based, nucleic acid based, and virus based methods to manufacture therapeutic proteins containing the HSA-PACC in a lab or industrial facility.

Sponsor shall reimburse the University for all Patent Related Expenses for University Background IP incurred by the University before and after the Effective Date of this Agreement. Payments are due within 30 days after receipt of University's invoice. "Patent-Related Expenses" means all costs and expenses (including out-of-pocket attorneys' fees, vendor charges, patent agent fees and governmental fees) that University incurs in preparing, filing, prosecuting, nationalizing, validating, registering, defending, and maintaining University Background IP. If University subsequently licenses the same University Background IP to one or more third party/ies outside the field for which Sponsor has exclusive rights, then University shall apportion the Patent Related Expenses equally between Sponsor and such third party/ies in accordance with applicable University policies on shared patent expenses.

- 8.6 **Reservation of Rights.** University retains an irrevocable, world-wide, royalty-free, non-exclusive right to use the Subject Inventions for teaching, research and educational purposes. The University shall have the right to sublicense its rights under this section to one or more non-profit academic or research institutions. If the University and Sponsor enters into a license agreement covering a Subject Inventions made under this Agreement, in case of a conflict between the terms of such license agreement and this Section 8.6, the terms of such license agreement shall control.

Article 9 - Termination

- 9.1 Either party may terminate this Agreement upon thirty (30) days prior written notice to the other. Upon submission/receipt of a notice of termination, University shall take measures to stop spending as soon as possible. A final report of the research conducted up to the effective date of termination, and the results and data obtained, and a high level accounting
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of the costs and expenses incurred in connection therewith, will be submitted within sixty (60) days of the termination date documenting all expenses incurred and all non-cancellable expenses which Sponsor is responsible for and showing the amount of funding overpaid or owed. If Sponsor has an unpaid balance remaining, Sponsor shall make the final payment within thirty (30) days after receipt of the final invoice. If Sponsor has overpaid, a check for the balance will be included within thirty (30) days of submission of the final accounting.

- 9.2 In the event of early termination of this Agreement by Sponsor pursuant to Article 9.1, Sponsor shall pay all costs incurred by University as of the date of termination, together with all non-cancellable obligations, which shall include all non-cancelable contracts, graduate assistantships, fellowships and postdoctoral associate appointments, entered into prior to the notice of termination. After termination, any obligation of Sponsor for fellowships, graduate assistantships or postdoctoral associates shall end no later than the end of University's academic year following termination.
 - 9.3 In the event of early termination of this agreement by University pursuant to Article 9.1 or by either party pursuant to Article 2.2, Sponsor shall pay only the costs incurred up to the date of termination.
 - 9.4 In the event that either party hereto shall commit any material breach of or default in any of the terms or conditions of this Agreement, and also shall fail to remedy such default or breach within ninety (90) days after receipt of written notice thereof from the other party hereto, unless such breach cannot reasonably be cured within such ninety (90) day period and the allegedly breaching party is working diligently to cure such material breach, the party giving notice may, at its option and in addition to any other remedies which it may have at law or in equity, terminate this Agreement by sending notice of termination in writing to the other party to such effect, and such termination shall be effective as of the date of the receipt of such notice.
 - 9.5 This Agreement may be terminated by written notice effective immediately by a Party upon the occurrence of any of the following with respect the other Party: (a) such other Party becomes insolvent, is dissolved or liquidated; (b) voluntary or involuntary proceedings by or against such other Party are instituted in bankruptcy or under any insolvency law, which proceedings, (i) if involuntary, shall not have been dismissed within ninety (90) days after the date of filing, and (ii) if voluntary, shall not have been instituted under Chapter 11 of the United States Bankruptcy Code, 11 U.S.C. §101 et seq.; (c) a receiver or custodian is appointed for such other Party, or proceedings are instituted by or against such other Party for the dissolution of such other Party, which proceedings, if involuntary, shall not have been dismissed within ninety (90) days after the date of filing; or (d) such other Party makes an assignment of substantially all of its assets for the benefit of its creditors, or substantially all of the assets of such other Party are seized or attached and not released within ninety (90) days thereafter. Subject to Article 8.6, termination of this Agreement by either party for any reason shall not affect the rights and obligations of the parties accrued prior to the effective date of termination of this Agreement. No termination of this Agreement, however effectuated, shall affect the Sponsor's rights and duties hereof, or release the
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parties hereto from their rights and obligations under Articles 4, 5, 6, 7, 8, 9, 11, 12, 13, 14 and 17.

Article 10 - Independent Contractor

It is expressly understood that University and Sponsor are independent contractors and not the agent, partner, or employee of the other. In this regard, neither party shall have the authority to enter into any contract or agreement to bind the other and shall not represent to anyone that it has such authority, nor shall their respective employees be entitled to any benefits applicable to employee of the other party.

Article 11 - Insurance and Indemnification

- 11.1 Each party represents that it has and will continue to have at least the following levels of insurance or self-insurance during the term of this Agreement: (i) as to the University, Workers' Compensation in statutory compliance with Minnesota State Law; and (ii) as to both parties, General Liability Insurance in an amount not less than one million dollars (\$1,000,000) per occurrence/two million dollars (\$2,000,000) annual aggregate. University represents that the University and Principal Investigator have and will continue to have Professional Liability insurance in an amount not less than one million dollars (\$1,000,000) per occurrence/two million dollars (\$2,000,000) annual aggregate. Sponsor represents that it has and will continue to have Product Liability insurance or self-insurance in an amount not less than one million dollars (\$1,000,000) per occurrence/two million dollars (\$2,000,000) annual aggregate. Certificates of all insurance detailed above shall be furnished to the other party upon request.
 - 11.2 Each party shall be responsible for its own acts and the results thereof and not for the acts of the other party. Liability of the University is subject to the terms and limitations of the Minnesota Tort Claims Act, Minnesota Statutes Section 3.736.
 - 11.3 Sponsor shall indemnify, defend, and hold harmless University against any and all third party claims, costs, or liabilities, including attorneys' fees and court costs at both trial and appellate levels, for any loss, damage, injury, or loss of life (other than that attributable to willful, wanton or intentional acts or omissions of the University, or University's breach of this Agreement or violation of applicable laws) arising out of use by Sponsor or any third party acting on behalf of or under authorization from Sponsor of information, reports, discoveries, deliverables, materials, products or other results of University's work under this Agreement or work otherwise associated with the Project. Article 11.3 shall apply with the provision that (a) University promptly notifies Sponsor in writing after University receives notice of any claim, (b) Sponsor is given the right to control such defense and trial of any claim and any related settlement negotiations (however Sponsor will not admit fault or liability on behalf of University without University approval, which will not be unreasonably withheld) and (c) University fully cooperates with Sponsor in the defense of any such claim.
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Article 12 – Representations and Warranties

University makes no warranties, express or implied, as to any matter whatsoever, including without limitation, the condition, originality or accuracy of the research or any invention (s) or product(s), whether tangible or intangible, conceived, discovered, or developed under this Agreement, or the ownership, merchantability, or fitness for a particular purpose of the research or any such invention or product. Each Party hereby represents and warrants to the other Party that (a) such Party is duly organized, validly existing and in good standing under the laws of its jurisdiction of incorporation or organization; (b) such Party is qualified or licensed to do business and in good standing in every jurisdiction where such qualification or licensing is required; (c) the execution and delivery of this Agreement and the performance by such Party of its obligations hereunder have been duly authorized by all requisite corporate action on its part; and (d) this Agreement has been validly executed and delivered by such Party, and constitutes a valid and binding obligation of such Party, enforceable against such Party in accordance with its terms except as enforceability may be limited by liquidation, bankruptcy, insolvency, reorganization, moratorium, formal restructuring, or other similar laws relating to or affecting creditors' rights generally or general principles of equity (regardless of whether enforcement is sought in a Proceeding in equity or at law).

Each Party represents and warrants to the other Party that: ~~(a)~~ such Party and its affiliates and contractors: (a) are skilled and experienced and capable in a manner consistent with the biopharmaceutical industry of performing work or providing materials or instructions in connection this Agreement or in their use of the Project results generated by University, (b), Such Party has obtained, and will maintain throughout the Term of this Agreement, any permits or approvals and otherwise comply with Applicable Laws relating to their performance of work or provision of materials or instructions in connection with this Agreement or in their use of results generated by University; (c) such Party shall comply with all Applicable Laws applicable to the conduct of their business activities relevant to their use of Project results generated by University; pursuant to this Agreement; and (d) there is no proceeding pending, or to the actual knowledge of such Party, threatened against such Party, which is likely to prevent or interfere with such Party's performance of work or provision of materials or instructions in connection with this Agreement or in their use of results generated by University.

Article 13 – LIMITATION OF LIABILITY FOR BREACH OF CONTRACT

IN NO EVENT SHALL EITHER PARTY'S LIABILITY FOR BREACH OF CONTRACT INCLUDE DAMAGES FOR WORK STOPPAGE, LOST DATA, OR INDIRECT, SPECIAL OR CONSEQUENTIAL DAMAGES (INCLUDING LOST PROFIT), OF ANY KIND. THE UNIVERSITY'S LIABILITY TO SPONSOR FOR BREACH OF THIS AGREEMENT SHALL NOT EXCEED THE MONETARY CONSIDERATION PAID TO THE UNIVERSITY UNDER THIS AGREEMENT. EXCEPT FOR SPONSOR'S INDEMNIFICATION OBLIGATIONS UNDER SECTION 11.3, SPONSOR'S LIABILITY TO THE UNIVERSITY FOR BREACH OF THIS AGREEMENT SHALL NOT EXCEED THE MONETARY CONSIDERATION DUE UNDER THIS AGREEMENT.

Article 14 - Governing Law and Jurisdiction

The internal laws of the state of Minnesota shall govern this Agreement, without giving effect to its conflict of laws principles. All suits, actions, claims and causes of action relating to the construction, validity, performance and enforcement of this Agreement shall be in the courts of Hennepin County, Minnesota.

Article 15 - Assignment

The parties may not assign any rights or obligations of this Agreement without the prior written consent of the other party. Any assignment attempted to be made in violation of this Agreement shall be void.

Article 16 - Agreement Modification

This Agreement shall be amended only in writing duly executed by all the parties to this Agreement. No waiver by any party of any default or nonperformance shall be deemed a waiver of any subsequent default or nonperformance.

Article 17 - Notices

Notices, requests, invoices, or communications, hereunder shall be deemed made upon submission to an overnight courier service or priority United States Mail, or three days after mailing by United States, first-class mail, certified or registered, postage prepaid, and addressed to the party to receive such notice, invoice, or communication at the address given below, or such other address as may hereafter be designated by notice in writing:

If to Sponsor:
Michael Breen
Executive Chairman &
Chief Executive Officer (Interim)
GT Biopharma, Inc.
8000 Marina Boulevard
Brisbane, CA 94005
Email: mb@gtbiopharma.com

If to University:
Sarah Danner
Sponsored Projects Administration
University of Minnesota
450 McNamara Alumni Center
200 Oak Street S.E.
Minneapolis, MN 55455-2070
Telephone: (612) 626-0270
E-Mail: sndanner@umn.edu

with a copy to Principal Investigator
Jeffrey Miller, MD
420 Delaware Street SE
MMC 480
Minneapolis, MN 55455
Telephone: 612-626-4024
E-Mail: mille011@umn.edu

If to University's Office for Technology Commercialization under Section 8.5:

Office for Technology Commercialization:
University of Minnesota
280 McNamara Alumni Center
200 Oak Street S.E.
Minneapolis, MN 55455-2070
Telephone: (612) 624-0550
Fax : (612) 624-6554
E-Mail: umotc@umn.edu

Article 18 - Force Majeure

No party to this Agreement shall be responsible for any delays or failure to perform any obligation under this Agreement due to acts of God, strikes or other disturbances, including, without limitation, war, insurrection, embargoes, pandemics, governmental restrictions, acts of governments or governmental authorities, and any other cause beyond the control of such party.

Article 19 - Entire Agreement

This Agreement (including all attached or referenced exhibits, schedules, appendices, addenda, or other documents) (collectively, the "Attachments") is intended by the parties as the final and binding expression of their agreement and as the complete and exclusive statement of its terms. This Agreement cancels, supersedes and revokes all prior negotiations, representations and agreements among the parties, whether oral or written, relating to the subject matter of this Agreement, including any non-disclosure or confidentiality agreements. To the extent the Attachments contain any terms and conditions that conflict with the terms and conditions of this Agreement or which materially change or add to the terms and conditions contained in this Agreement, such changes will be ignored and given no effect.

Article 20 – Severability

If any provision of this Contract becomes or is declared illegal, invalid, or unenforceable, the provision will be divisible from this Contract and deemed to be deleted from this Agreement. If the deletion substantially alters the basis of this Contract, the parties will negotiate in good faith to amend the provisions of this Contract to give effect to the original intent of the parties.

Article 21 – Compliance

Each Party represents and warrants that neither it nor any of its or its Affiliates' employees or agents performing under this Agreement has ever been, or is currently: (a) debarred under 21 U.S.C. § 335a or by any regulatory authority; (b) excluded, debarred, suspended, or otherwise ineligible to participate in federal health care programs or in federal procurement or non-procurement programs; (c) listed on the FDA's Disqualified and Restricted Lists for clinical investigators; or (d) convicted of a criminal offense that falls within the scope of 42 U.S.C. § 1320a-7(a), but has not yet been excluded, debarred, suspended, or otherwise declared ineligible. Each Party further covenants that if, during the Term of this Agreement, it becomes aware that it or any of its or its Affiliates' employees or agents performing under this Agreement is the subject

of any investigation or proceeding that could lead to that Party becoming a debarred entity or individual, an excluded entity or individual or a convicted entity or individual, in each case pursuant to subsections (a) through (d) of this Section 10.1, such Party will promptly notify the other Party. Each Party further covenants that if, during the Term of this Agreement, it becomes aware that it or any of its or its Affiliates' employees or agents is the subject of any investigation or proceeding that could lead to that entity becoming a debarred entity or individual, an excluded entity or individual or a convicted entity or individual, in each case pursuant to subsections (a) through (d) of this Section 10.1, such Party will promptly notify the other Party in writing.

Article 21 – Counterparts

This Agreement may be signed in counterparts, each of which shall be deemed one and the same original.

IN WITNESS WHEREOF, the undersigned have executed this Agreement as of the date first written above.

**REGENTS OF THE UNIVERSITY OF
MINNESOTA**

SPONSOR

BY: DocuSigned by:
Sarah Danner
4D489CFA0A344B2...
Sarah Danner

BY: DocuSigned by:
Michael Breen
2B4E7E3B6E9D94CF...
Michael Breen

TITLE: Senior Grant and Contract Administrator

TITLE: Executive Chairman & Chief Executive Officer (Interim)

DATE: _____

DATE: _____

I have read the above Agreement and agree to perform my obligations as principal investigator(s) under this agreement. I also understand and agree to the disposition of rights in inventions, discoveries, and other results as provided by this agreement and to the provisions concerning confidentiality and publications. I will inform students and other participants working on this research of their rights and obligations under this agreement.

Principal Investigator
DocuSigned by:
BY: Jeffrey Miller, MD
D69D5C19E87948C...
Jeffrey Miller, MD

Co-Principal Investigator *(If Applicable)*
BY: _____

TITLE: Professor of Medicine

TITLE: _____

DATE: _____

DATE: _____

- Appendices:
Appendix 1– Description of the Research Project
Appendix 2 – Project Budget
Appendix 3 – License Options

Appendix 1 – Description of the Research Project

This scientific research agreement aims to continue our work with GT Biopharma with three major goals in mind: (1) support of GT Biopharma's TriKE product development and commercial GMP manufacturing efforts; (2) TriKE pharmacokinetics optimization in humans and investigation of effects of altering the route of administration; and (3) R&D of TriKE platform. The major deliverables proposed here are: (1) creation of IND enabling data for TriKE constructs in support of GT Biopharma product development and commercial GMP manufacturing efforts outside of UMN; (2) TriKE platform drug delivery changes to allow transition from intravenous (IV) continuous infusion to alternative drug delivery administration (IV bolus, intraperitoneal [IP], subcutaneous [SQ]) and extended PK in humans and gain an increased understanding of changes in the patient's native NK cell population as a result of alteration of TriKE administration; and (3) Research and Development of TriKE platform combination with other FDA approved (or soon to be approved) therapeutics and alterations to TriKE platform through formation of immune complexes. Most studies will use TriKE DNA/amino acid sequences licensed to GT Biopharma under current UMN/GTB terms, but Specific Aim 3B requires a new license.

Specific AIM #1:

A. Provide NK cell functional and preclinical evaluation of TriKE products produced under cGMP Cytovance (or qualified contract manufacturer) for clinical and/or commercial development. Studies will analyze TriKE Product Candidates for *in vitro* and *in vivo* function including but not limited to:

1. CD107a degranulation assay
2. NK cell proliferation assay
3. Target cancer cell surface marker blocking studies
4. *in vivo* xenogeneic mouse targeted tumor model studies
5. InCuCyte/xCELLigence killing assays

B. Studies will also be conducted in support of filing of Investigational New Drug applications related to the evaluation of TriKE Product Candidates in human clinical trials:

1. Dose Finding Studies for GTB-5550.
2. In use studies to evaluate efficient delivery of drug using pumps and tubing that will be used in the clinical trials (GTB-3650 [will start under current SRA] and GTB-5550)
3. In vivo studies for GTB-5550 for support of IND application.

C. Potency release assay testing for cGMP products (release and stability):

1. For GTB-3650 the University of Minnesota, under the direction of Dr. Zachary Davis or other principal investigator, approved by the University and in accordance with UMN policies including, but not limited to, the conflict management plan of Drs. Miller and Felices will conduct potency testing (release and stability) on GTB-3650 samples using the CD107a assay.
2. For GTB-5550 the University of Minnesota, under the direction of Dr. Zachary Davis or other principal investigator, approved by the University and in accordance with UMN policies including, but not limited to, the conflict management plan of Drs. Miller and Felices who will conduct potency testing (release and stability) of cGMP produced GTB-5550 using the CD107a assay. This will be done for release and stability of the drug substrate and the drug product, unless Labcorp can produce a cGMP competent assay prior to the trial.

Specific AIM #2:

- A. Investigate ways to improve pharmacokinetics (PK) of GT Biopharma's TriKE Product Candidates:
 1. Evaluate different routes of administration (SQ and bolus IV) in xenogeneic mouse models.
 2. Evaluate TriKE trafficking in vivo (e.g. copper labelling [or other]): note that this would require an internal collaboration to get proper expertise to carry this out.
 3. Determine the best dosing frequency to sustain efficacy in pre-clinical models.
 4. Understand the trafficking of NK cells from blood to tissue with dosing strategy (pre-clinical models).
 5. ADA (Anti-Drug Antibody) studies for GTB-3650 and GTB-5550 trials to evaluate potential for decreased activity mediated by ADA. *NOTE: The ADA studies, which evaluate formation of Anti-Drug Antibodies in the blood of treated patients, are FDA reportable and therefore will be carried out under the clinical agreement workscope. However, those studies do not determine if the antibodies that form impact the actual functionality of the TriKE; those assays are not reportable, are quite specialized, and will be carried out under this SRA.*

Specific AIM #3:

- A. Evaluate use of possible combination therapeutic strategies with TriKE.
 - a. Evaluate the effect of TriKE with NK cell products in development with other companies. The primary focus will be with GTB's clinical candidates (GTB-3650 and GTB-5550) by mutual agreement GTB under the terms of this SRA and UMN licensing agreements.
 - b. Evaluate combination of TriKE with already approved standard of care regimens (checkpoint blockade antibodies, Venetoclax, Azacytadine, etc).
 - B. Evaluate alterations to TriKE platform (with the understanding that these projects might extend beyond 2-year mark):
 - a. Develop 3rd generation TriKE-PACC (Poly-Antigen Cytokine-receptor Complex) molecules designed for optimal PK*:
 - i. Evaluate TriKE-PACC approach for maximum PK using incorporation of Human Serum Albumin (HSA) arm in PACC. Examples of this encompass TriKEs (already licensed to GT Biopharma) like:
 1. Anti-CD33 TriKE (GTB-3650) combined with HSA PACC molecule: 33/HSA TriKE-PACC.
 2. Anti-B7H3 TriKE (GTB-5550) combined with HSA PACC molecule: B7H3/HSA TriKE-PACC.
 3. Or other TriKE molecules, for instance anti-HER2 TriKE combined with HSA PACC molecule: HER2/HSA TriKE PACC.
 - b. Create dual targeting "3rd generation" TriKEs using PACC*:
 - i. Create and evaluate dual-targeting molecules using an anti-HER2 PACC (for treatment of solid tumors). Examples of this encompass TriKEs (already licensed to GT Biopharma) like:
 1. Anti-B7H3 TriKE (GTB-5550) combined with anti-HER2 PACC molecule: B7H3/HER2 TriKE-PACC.
 2. Or other TriKE molecules, for instance anti-CD133 TriKE or anti-PDL1 TriKE combined with HER2 PACC molecule: 133/HER2 TriKE-PACC and PDL1/HER2 TriKE-PACC (respectively).
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Appendix 3 – License Options

		TriKE Engager or Other Domain (Other than PACC)	PACC (University Background IP only) UMN case #2024-041	PACC (Modified Under the SRA)	Non-TriKE (Inventions Unrelated to TriKEs)
1	License grant	Exclusive	Exclusive	Exclusive	Exclusive
2	Fields of use(s)	All fields	As set forth in Section 8.5.2 hereof.	All fields; (As set forth in Section 8.5.1 and 8.5.2)	All fields
3	License Upfront fee	\$15k	\$25k	\$15k	\$15k
4	Annual license fee	Governed by Section 11.2 of the AREPLA. No additional annual fee due for this license.	Additional payment of: \$10K first and second anniversary, \$15K thereafter	Governed by Section 11.2 of the AREPLA. No additional annual fee due for this license.	\$25k per year, first and second anniversary. \$50k per year thereafter.
5	Milestone payments	Governed by Section 11.8.1 of the AREPLA. No further milestones payable for this license.	Governed by Section 11.8.1 of the AREPLA. One additional Milestone payment of \$500,000 is due when the Licensee achieves the first commercial sale of a Licensed Product which incorporates PACC.	Governed by Section 11.8.1 of the AREPLA. No further milestones payable for this license.	Same as Section 11.8.1 of the AREPLA
6	Sales Milestones	Governed by Section 11.8.3 of the AREPLA. No further milestones payable for this license.	Governed by Section 11.8.3 of the AREPLA. No further milestones payable for this license.	Governed by Section 11.8.3 of the AREPLA. No further milestones payable for this license.	Same as Section 11.8.3 of the AREPLA
7	Royalties	1.5% (subject to stacking and overall royalty cap per Section 11.4 of the AREPLA)	1% (subject to stacking and overall royalty cap per Section 11.4 of the AREPLA)	1% (subject to stacking and overall royalty cap per Section 11.4 of the AREPLA)	2% (subject to stacking and overall royalty cap per Section 11.4 of the AREPLA)
8	Annual Minimum Royalties	Governed by Section 11.5 of the AREPLA. No additional annual	Governed by Section 11.5 of the AREPLA. No additional annual minimum	Governed by Section 11.5 of the AREPLA. No additional annual	Same as Section 11.5 of the AREPLA.

		minimum royalties due for this license.	royalties due for this license.	minimum royalties due for this license.	
9	Sublicense consideration	Governed by Section 11.6 of the AREPLA. No separate sublicense consideration due for this license.	Governed by Section 11.6 of the AREPLA. No separate sublicense consideration due for this license. Licensee agrees that it will not sublicense U's PACC Technology independent of U's TriKE Licensed Product(s).	Governed by Section 11.6 of the AREPLA. No separate sublicense consideration due for this license.	Same as Section 11.6 of the AREPLA.
10	Change of Control	Governed by Section 11.7 of the AREPLA. No separate fee payable for the license.	Governed by Section 11.7 of the AREPLA. No separate fee payable for the license.	Governed by Section 11.7 of the AREPLA. No separate fee payable for the license.	\$175,000
11	Performance Milestones	Same as in Section 9 of the AREPLA. Dates to be negotiated based on each invention.	Same as in Section 9 of the AREPLA. Dates to be negotiated based on each invention.	Same as in Section 9 of the AREPLA. Dates to be negotiated based on each invention	Same as in Section 9 of the AREPLA. Dates to be negotiated based on each invention.
12	Document fee	None	None	None	None
13	Early termination fee	None	None	None	As set forth in Section 8.3 of the Terms and Conditions.
14	License amendment fee	None	\$5,000	None	None
15	Restrictions on University Retained Rights	Applicable as set forth in Section 3.2 of the Terms and Conditions to the AREPLA.	To be negotiated on a case-by-case basis.	Applicable as set forth in Section 3.2 of the Terms and Conditions to the AREPLA, subject to the University obtaining internal consents from affected faculty and departments.	Applicable as set forth in Section 3.2 of the Terms and Conditions to the AREPLA, subject to the University obtaining internal consents from affected faculty and departments.

All references in this Appendix 3 to the AREPLA shall mean the Amended and Restated Exclusive Patent License Agreement between the University and Sponsor dated May 13, 2024.



CERTIFICATION PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT

I, Michael Breen, certify that:

- a. I have reviewed this report on Form 10-Q of GT Biopharma, Inc.;
- b. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
- c. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
- d. I am responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
 - i) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
 - ii) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
 - iii) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
 - iv) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
- e. I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's Board of Directors (or persons performing the equivalent functions):
 - i) all significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
 - ii) any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: August 14, 2024

By: /s/ Michael Breen

Name: Michael Breen

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

CERTIFICATION PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT

I, Alan Urban, certify that:

- a. I have reviewed this report on Form 10-Q of GT Biopharma, Inc.;
- b. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
- c. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
- d. I am responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f) for the registrant and have:
 - i) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
 - ii) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
 - iii) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
 - iv) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
- e. I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's Board of Directors (or persons performing the equivalent functions):
 - i) all significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
 - ii) any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: August 14, 2024

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

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

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

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

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

Date: August 14, 2024

By: /s/ Michael Breen

Name: Michael Breen

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

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

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

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

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

Date: August 14, 2024

By: /s/ Alan Urban

Name: Alan Urban

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