November 14, 2024

GT Biopharma Reports Third Quarter 2024 Financial Results

- *GTB-3650 TriKE® Phase 1 trial first patient dosed expected in Q4 2024; initial clinical data expected in Q2 2025*
- *GTB-5550 TriKE® IND submission for treatment of B7H3 positive solid tumors expected in 1H 2025*
- *GTB-5550 Phase 1 dose escalation basket trial initiation expected in 2025 evaluating multiple solid tumor types, including prostate, breast, head and neck, ovarian, lung, liver, and GI*
- *GTB-7550 TriKE® targets CD19 and is in preclinical development for the treatment of Lupus and other autoimmune indications*
- *Cash of approximately $6.5 million as of September 30, 2024, anticipated to be sufficient to fund operations into Q2 2025*

SAN FRANCISCO, CALIFORNIA, Nov. 14, 2024 (GLOBE NEWSWIRE) -- GT Biopharma, Inc. (the "Company") (NASDAQ: GTBP), a clinical stage immuno-oncology company focused on developing innovative therapeutics based on the Company's proprietary natural killer (NK) cell engager TriKE® platform, today announced third quarter 2024 financial results for the period ended September 30, 2024.

"We are pleased to be progressing towards dosing the first patient in our Phase 1 trial evaluating GTB-3650 in cancer patients in the fourth quarter of this year. This dose escalation study will evaluate GTB-3650 in 12 patients (six cohorts) with relapsed or refractory (r/r) CD33 expressing hematologic malignancies, including refractory acute myeloid leukemia (AML) and high-risk myelodysplastic syndrome (MDS). We believe that NK cell engagers, like GTB-3650, have the potential to offer patients with a safer alternative to current treatments, like CAR-T therapy", said Michael Breen, Executive Chairman and interim Chief Executive Office of GT Biopharma.

This past October, the company held a virtual KOL event featuring Jeffrey Miller, MD[1] and Mark Juckett, MD from the University of Minnesota Medical School[2] who spoke to the value of NK cells within the broader therapeutic landscape as well as the potential for GT Biopharma's NK cell engager pipeline, and specifically GTB-7550 which targets CD19 for autoimmune indications. "As a company, we are especially excited to continue exploring opportunities where our TriKE platform technology may have therapeutic utility, especially

for autoimmune indications and in combination with NK cell therapies", said Michael Breen. "In this rapidly emerging field, combination approaches may offer us the opportunity to leverage our patented platform technology across multiple NK cell engager constructs with new targets and for additional diseases.

1. Dr. Miller is the Consulting Senior Medical Director at GT Biopharma and holds stock and options in GTBP.
2. The University of Minnesota, pursuant to its license agreement with GT Biopharma, is entitled to receive royalties should commercial sales of GTB-3650 be realized. This interest has been reviewed and managed by the University of Minnesota in accordance with its conflict of interest policies.

Third Quarter 2024 Financial Summary

Cash Position: The Company had cash and cash equivalents of approximately $6.5 million as of September 30, 2024, anticipated to be sufficient to fund operations into Q2 2025.

Research and Development (R&D) Expenses: R&D expenses for the third quarter ended September 30, 2024 were $1.3 million, flat compared to the same comparable quarter of 2023, primarily due to a reduction in raw material costs and 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 of other promising candidates. In late June 2024, we received clearance from the FDA with respect to its IND Application in relation to GTB 3650. We anticipate the direct clinical and preclinical expenses to increase in 2024 as we advance GTB-3650 into the clinic and enroll patients, perform tests for data collection, complete the product development of GTB-5550, and anticipate submission of an 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 (SG&A) Expenses (Excluding Stock Compensation): SG&A expenses for the third quarter ended September 30, 2024 were $2.3 million compared to $1.2 million for the same comparable quarter of 2023, the $1.1 million increase was primarily due to an increase in legal and professional fees and for the probable settlement of a legal matter.

Other Income: Other income for the third quarter ended September 30, 2024 was $193,000 compared to $706,000 for the same comparable quarter of 2023, the decrease was primarily due to a $390,000 reduction in the non-cash change in fair value of warrant liability.

Net Loss: The Company reported a net loss of $3.4 million for the third quarter ended September 30, 2024 compared to a net loss of $2.4 million for the same comparable quarter in 2023. The $1 million increase in net loss consisted primarily of a $390,000 reduction in the non-cash change in fair value of warrant liability and a $1.2 million increase in SG&A expenses (as described above), partially offset by a $547,000 decrease in stock compensation expense.

About GT Biopharma, Inc.

GT Biopharma, Inc. is a clinical stage biopharmaceutical company focused on the

development and commercialization of immuno-oncology therapeutic products based on our proprietary TriKE® NK cell engager platform. Our TriKE® platform is designed to harness and enhance the cancer killing abilities of a patient's immune system's natural killer cells. GT Biopharma has an exclusive worldwide license agreement with the University of Minnesota to further develop and commercialize therapies using TriKE® technology. For more information, please visit gtbiopharma.com.

Forward-Looking Statements

Certain statements in this press release may constitute "forward-looking statements" regarding future events and our future results. All statements other than statements of historical facts are statements that could be deemed to be forward-looking statements. These statements are based on current expectations, estimates, forecasts, and projections about the markets in which we operate and the beliefs and assumptions of our management. Words such as "expects," "anticipates," "targets," "goals," "projects", "intends," "plans," "believes," "seeks," "estimates," "endeavors," "strives," "may," or variations of such words, and similar expressions are intended to identify such forward-looking statements. Readers are cautioned that these forward-looking statements are subject to a number of risks, uncertainties and assumptions that are difficult to predict, estimate or verify. Therefore, actual results may differ materially and adversely from those expressed in any forward-looking statements. Such risks and uncertainties include those factors described in our most recent annual report on Form 10-K, as such may be amended or supplemented by subsequent quarterly reports on Form 10-Q, or other reports filed with the Securities and Exchange Commission. Readers are cautioned not to place undue reliance on these forward-looking statements. The forward-looking statements are made only as of the date hereof, and we undertake no obligation to publicly release the result of any revisions to these forward-looking statements. For more information, please refer to our filings with the Securities and Exchange Commission.

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GT BIOPHARMA, INC. AND SUBSIDIARIES
Condensed Consolidated Balance Sheets

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

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

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

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

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

Source: GT Biopharma, Inc.