May 15, 2024

GT Biopharma Reports First Quarter 2024 Financial Results and Provides Corporate Update

- *IND clearance for GTB-3650, a 2nd generation nanobody TriKE® for treatment of CD33+ leukemia expected in Q2 2024*
- *Phase 1 trial initiation with GTB-3650 expected in 2H 2024*
- *Anticipate IND submission for GTB-5550 TriKE® for treatment of B7H3 positive solid tumors in Q4 2024*
- *Plan to initiate a Phase 1 dose escalation basket trial evaluating GTB-5550 in six solid tumor cancers – prostate, breast, head and neck, ovarian, lung, and GI*
- *Cash of approximately $9.81 million as of March 31, 2024,provides sufficient runway to fund operations into 2025*

BRISBANE, CALIFORNIA, May 15, 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 first quarter 2024 financial results for the period ended March 31, 2024.

"As we continue to work towards FDA clearance of the IND for GTB-3650, we look forward to submitting a second IND later this year for GTB-5550. By targeting B7H3, GTB-5550's potential target market within solid tumors increases multifold", said Michael Breen, Executive Chairman and interim Chief Executive Office of GT Biopharma. "We expect the next 18 months to be an eventful period for the Company with substantial clinical activity followed by data readouts. Our Phase 1 trial evaluating GTB-3650 in AML patients is anticipated to start this year, followed by a basket trial with GTB-5550 for multiple solid tumors in early 2025. We also remain active in exploring additional opportunities where our TriKE's may have therapeutic utility, including autoimmune indications."

First Quarter 2024 Financial Summary

Cash Position: The Company had cash, cash equivalents and short-term investments of $9.81 million as of March 31, 2024 compared to $13.97 million as of December 31, 2023. This is anticipated to provide sufficient runway to fund operations into 2025.

Research and Development (R&D) Expenses: R&D expenses for the first quarter ended March 31, 2024 were $777,000 compared to $1.65 million for the same comparable quarter of 2023. R&D expenses decreased by $873,000 primarily due to reduction in raw material purchases of $657,000 as we benefit from the near completion of product development of

GTB 3650 and advance product development of GTB 5550, and reduction of $216,000 in consulting fees due to better management of other research and development costs. We anticipate the direct clinical and preclinical expenses to continue 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 fourth quarter of 2024. We do not, however, anticipate an increase in related R&D licensing and administrative costs.

Selling, General and Administrative (SG&A) Expenses: SG&A expenses for the first quarter ended March 31, 2024 were $2.31 million compared to $2.02 million for the same comparable quarter of 2023. SG&A expenses increased by $299,000 for the comparable periods, primarily due to reduction in stock-based compensation expense for officers, employees and board of directors by $616,000, offset by an increase in legal and professional fees of $794,000 and an increase in costs of filing regulatory fees and other SG&A expenses of $121,000.

Other Income and expense: Other income net of other expenses, for the first quarter ended March 31, 2024 was $825,000 compared to $3.44 million for the same comparable quarter of 2023. Other income and expense consisted of interest income, interest expense, change in the fair value of warrant liability, gain on extinguishment of debt, and unrealized gain and loss on marketable securities. The overall reduction in other income net of expenses for the three months ended March 31, 2024 as compared to the prior year, was primarily due to the change in fair value of warrant liability as a result of fair value remeasurement which resulted in a smaller gain of $658,000 in the quarter ended March 31, 2024 compared to a gain of $2.92 million in the prior year comparable quarter. Additionally, interest expense and gain on extinguishment of debt resulted in a net gain of $321,000 recorded in quarter ended March 31, 2023, with no similar gains recorded in the quarter ended March 31, 2024.

Net Loss: The Company reported a net loss of $2.27 million for the first quarter ended March 31, 2024 compared to a net loss of $227,000 for the same comparable quarter in 2023.

About Camelid Antibodies

Camelid antibodies are single domain antibodies (sdAbs) from the Camelidae family of mammals that include llamas, camels, and alpacas. These animals produce two main types of antibodies. One type of antibody camelids produce is the conventional antibody that is made up of two heavy chains and two light chains. They also produce another type of antibody that is made up of only two heavy chains and no light chain. This is known as heavy chain IgG (hcIgG). While these antibodies do not contain the CH1 region, they retain an antigen binding domain called the VHH region. VHH antibodies, also known as single domain antibodies, contain only the VHH region from the camelid antibody. Camelid antibodies have key characteristics, which include high affinity and specificity (equivalent to conventional antibodies), high thermostability, good solubility and strictly monomeric behavior, small size, relatively low production cost, ease of genetic engineering, format flexibility or modularity, low immunogenicity, and a higher penetration rate into tissues.

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
(in thousands, except shares and par value)

	March 31, 2024	December 31, 2023
	(Unaudited)	
ASSETS		
Current assets		
Cash and cash equivalents	$ 1,950	$ 1,079
Short-term investments	7,857	12,893
Prepaid expenses and other current assets	78	84
Total Current Assets	9,885	14,056
Operating lease right-of-use asset	27	53
TOTAL ASSETS	$ 9,912	$ 14,109
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities		
Accounts payable	$ 3,213	$ 4,328
Accrued expenses	963	1,195
Current operating lease liability	30	58
Warrant liability	394	1,052
Total Current Liabilities	4,600	6,633
Total Liabilities	$ 4,600	$ 6,633
Stockholders' Equity		
Convertible Preferred stock, par value $0.01, 15,000,000 shares authorized Series C - 96,230 shares issued and outstanding at March 31, 2024 and December 31, 2023, respectively	1	1
Common stock, par value $0.001, 250,000,000 shares authorized, 1,380,633 shares issued and outstanding as of March 31, 2024 and December 31, 2023, respectively	1	1
Additional paid in capital	689,641	689,539
Accumulated deficit	(684,331)	(682,065)
Total Stockholders' Equity	5,312	7,476
TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY	$ 9,912	$ 14,109

GT BIOPHARMA, INC. AND SUBSIDIARIES
Condensed Consolidated Statements of Operations
(in thousands, except per share data)

	For The Three Months Ended March 31,	
	2024	2023
	(unaudited)	(unaudited)
Revenues	$ -	$ -
Operating Expenses:		
Research and development	777	1,650
Selling, general and administrative (including $102 and $718 from stock compensation granted to officers, directors and employees during the three months ended March 31, 2024 and 2023, respectively)	2,314	2,015
Loss from Operations	3,091	3,665
Other (Income) Expense		
Interest income	(142)	(164)
Interest expense	-	212
Change in fair value of warrant liability	(658)	(2,924)
Gain on extinguishment of debt	-	(533)
Unrealized loss (gain) on marketable securities	2	(29)
Other	(27)	-
Total Other (Income) Expense	(825)	(3,438)
Net Loss	$ (2,266)	$ (227)
Net Loss Per Share - Basic and Diluted	$ (1.64)	$ (0.21)
Weighted average common shares outstanding - basic and diluted	1,380,633	1,082,871

GT BIOPHARMA, INC. AND SUBSIDIARIES
CONDENSED CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY
(in thousands)

For The Three Months Ended March 31, 2024 (Unaudited)

	Preferred Shares		Common Shares		Additional Paid in	Accumulated	
	Shares	Amount	Shares	Amount	Capital	Deficit	Total
Balance, December 31, 2023	96	$ 1	1,381	$ 1	$ 689,539	$ (682,065)	$ 7,476
Fair value of vested stock options	-	-	-	-	102	-	102
Net loss	-	-	-	-	-	(2,266)	(2,266)
Balance, March 31, 2024	96	$ 1	1,381	$ 1	$ 689,641	$ (684,331)	$ 5,312

For The Three Months Ended March 31, 2023 (Unaudited)

	Preferred Shares		Common Shares		Additional Paid in	Accumulated	
	Shares	Amount	Shares	Amount	Capital	Deficit	Total
Balance, December 31, 2022	96	$ 1	1,091	$ 1	$ 686,200	$ (674,468)	$ 11,734
Private placement of common stock	-	-	120	-	6,268	-	6,268
Initial recognition of fair value of warrant liability	-	-	-	-	(5,831)	-	(5,831)
Fair value of vested stock options	-	-	-	-	507	-	507
Issuance of common shares for services	-	-	2	-	315	-	315
Issuance of common shares in settlement of vendors payable	-	-	16	-	287	-	287
Net loss	-	-	-	-	-	(227)	(227)
Balance, March 31, 2023	96	$ 1	1,229	$ 1	$ 687,746	$ (674,695)	$ 13,053

GT BIOPHARMA, INC. AND SUBSIDIARIES
Condensed Consolidated Statements of Cash Flows
(in thousands)

	For The Three Months Ended March 31,	
	2024	2023
	(Unaudited)	(Unaudited)
CASH FLOWS FROM OPERATING ACTIVITIES		
Net loss	$ (2,266)	$ (227)
Adjustments to reconcile net loss to net cash used in operating activities:		
Stock based compensation - services	-	176
Stock based compensation - officers, employees and board of directors	102	646
Change in fair value of warrant liability	(658)	(2,924)
Gain on extinguishment of share settled debt	-	(533)
Change in operating lease right-of-use assets	26	25
Unrealized loss (gain) on marketable securities	2	(29)
Changes in operating assets and liabilities:		
Decrease in prepaid expenses	6	16
(Decrease) in accounts payable and accrued expenses	(1,347)	(29)
(Decrease) in operating lease liability	(28)	(27)
Net Cash Used in Operating Activities	(4,163)	(2,906)
CASH FLOWS FROM INVESTING ACTIVITIES		
Sale (purchase) of investments	5,034	(6,989)
Net Cash Provided by (Used in) Investing Activities	5,034	(6,989)
CASH FLOWS FROM FINANCING ACTIVITIES		
Proceeds from issuance of common stock and prefunded warrants	-	6,268
Net Cash Provided by Financing Activities	-	6,268
Net Increase (Decrease) in Cash	871	(3,627)
Cash at Beginning of Period	1,079	5,672
Cash at End of Period	$ 1,950	$ 2,045
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
Fair value of common stock issued to a vendor to settle accounts payable	$ -	$ 287

GT Biopharma, Inc.

Source: GT Biopharma, Inc.