

November 1, 2023



GT Biopharma Reports Third Quarter 2023 Financial Results

- *IND submission for GTB-3650, 2nd generation nanobody TriKE[®] for treatment of CD33+ leukemia, expected in Q4 2023*
- *Phase 1 clinical trial initiation evaluating GTB-3650 for treatment of CD33+ leukemia anticipated in 2024*
- *Cash of approximately \$16 million as of September 30, 2023, provides ample runway to fund operations into 2H 2024; anticipated to be sufficient to initiate clinical trial activities on GTB-3650*

BRISBANE, CALIFORNIA, Nov. 01, 2023 (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 2023 results for the period ended September 30, 2023.

"We continue to move forward in advancing our novel portfolio of TriKE[®] nanobody assets," said Michael Breen, Executive Chairman and interim Chief Executive Office of GT Biopharma. "We remain on track to submit an IND to the U.S. Food and Drug Administration (FDA) in Q4 2023 for GTB-3650, a second generation nanobody TriKE[®] for the treatment of CD33+ leukemia. Following FDA acceptance, we plan to host a KOL event highlighting the anticipated Phase 1 clinical trial design and timelines for data. Our current cash runway is sufficient to progress through multiple upcoming milestones in 2024, and we continue to actively explore potential development partnerships for our programs."

Third Quarter 2023 Financial Summary

Cash Position: The Company had cash, cash equivalents and short-term investments of \$16.01 million as of September 30, 2023 compared to \$17.97 million as of June 30, 2023. We expect ample runway to fund operations into 2H 2024.

Research and Development (R&D) Expenses: R&D expenses for the three months and nine months ended September 30, 2023 were \$1.36 million and \$5.11 million, compared to \$2.57 million and \$5.79 million for the same comparable periods of 2022. Research and development expenses are related 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 product candidates. R&D expenses decreased over the previous year primarily due to reduction of in-house staff offset with the increase in compensation to consultants as we prepare to advance our next generation GTB-3650 camelid nanobody product into the clinic.

General and Administrative (G&A) Expenses: G&A expenses for the three months and nine months ended September 30, 2023 were \$1.76 million and \$5.30 million, compared to \$4.46 million and \$9.69 million for the same comparable periods of 2022. The decrease in G&A expenses was primarily attributable to reduction in stock-based compensation to advisory board, investor relations consultants, legal and professional fees, and payroll expenses.

Other (Income) Expenses

The Company recorded interest income of \$0.22 million and \$0.60 million for the three months and nine months ended September 30, 2023, compared to \$0.11 million and \$0.15 million, for the same comparable periods in 2022. The increase in interest income was due to higher interest rates offered by financial institutions in the three months and nine months ended September 30, 2023 as compared to the same comparable periods of 2022. We recorded interest expense of \$0 and \$0.21 million for the three months and nine months ended September 30, 2023, compared to \$0 for the same comparable periods in 2022, respectively. The increase in interest expense was due to the financing costs incurred associated with warrants accounted as warrant liability sold during the current year, with no comparable costs in the prior year. The Company recorded a gain due to change in the fair value of warrant liability of \$0.49 million and \$4.80 million for the three months and nine months ended September 30, 2023, compared to a gain of \$0.06 million and \$0.08 million for the same comparable periods of 2022. The increase in gain resulted due to a change in the fair value of the warrant liability during the three months and nine months ended September 30, 2023. We recorded a gain on extinguishment of debt of \$0 and \$0.55 million for the three months and nine months ended September 30, 2023, compared to \$0 for the same comparable periods in 2022. The gain for the nine months ended September 30, 2023 was as a result of share settlement of a greater amount of vendor accounts payable than the fair value of the shares on the date of settlement.

Net Loss: The Company reported a net loss of \$2.42 million and \$4.64 million for the three months and nine months ended September 30, 2023, compared to a net loss of \$6.88 million and \$15.30 million for the same comparable periods in 2022.

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 (hclgG). 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.

TriKE[®] is a registered trademark owned by GT Biopharma, Inc.

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

	September 30, 2023 (Unaudited)	December 31, 2022
ASSETS		
Current assets		
Cash and cash equivalents	\$ 2,648	\$ 5,672
Short-term investments	13,366	10,836
Prepaid expenses and other current assets	38	54
Total Current Assets	16,052	16,562
Operating lease right-of-use asset	87	165
Deposits	9	9
TOTAL ASSETS	\$ 16,148	\$ 16,736
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities		
Accounts payable	\$ 3,970	\$ 3,140
Accrued expenses	1,028	1,669
Current operating lease liability	92	110
Total Current Liabilities	5,090	4,919
Non-current operating lease liability	-	64
Warrant liability	1,053	19
Total Liabilities	6,143	5,002
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, 2023 and December 31, 2022, respectively	1	1
Common stock, par value \$0.001, 250,000,000 shares authorized, 41,418,999 shares and 32,722,452 shares issued and outstanding as of September 30, 2023 and December 31, 2022, respectively	42	33
Additional paid in capital	689,065	686,168
Accumulated deficit	(679,103)	(674,468)
Total Stockholders' Equity	10,005	11,734
TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY	\$ 16,148	\$ 16,736

GT BIOPHARMA, INC. AND SUBSIDIARIES
CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS
(in thousands, except per share data)

	For The Three Months Ended September 30,		For the Nine Months Ended September 30,	
	2023	2022	2023	2022
	(Unaudited)	(Unaudited)	(Unaudited)	(Unaudited)
Revenues	\$ -	\$ -	\$ -	\$ -
Operating Expenses:				
Research and development (including \$0 and \$201 expense from stock compensation granted to officers, directors and employees during the three months ended September 30, 2023 and 2022, and \$13 and \$327 for the nine months ended September 30, 2023 and 2022, respectively)	1,364	2,743	5,109	5,969
Selling, general and administrative (including \$0.5 million and \$2.7 million expense from stock compensation granted to officers, directors and employees during the three months ended September 30, 2023 and 2022, respectively and \$1.8 million and \$3.5 million for the nine months ended September 30, 2023 and 2022, respectively)	1,758	4,280	5,299	9,510
Loss from Operations	(3,122)	(7,023)	(10,408)	(15,479)
Other (Income) Expense				
Interest income	(216)	(107)	(600)	(151)
Interest expense	-	-	213	-
Change in fair value of derivative liability	(485)	(58)	(4,796)	(81)
Gain on extinguishment of debt	-	-	(547)	-
Unrealized (gain) loss on short term investments	(5)	23	(43)	53
Total Other (Income) Expense	(706)	(142)	(5,773)	(179)
Net Loss	\$ (2,416)	\$ (6,881)	\$ (4,635)	\$ (15,300)
Net Loss Per Share - Basic and Diluted	\$ (0.06)	\$ (0.22)	\$ (0.12)	\$ (0.48)
Weighted average common shares outstanding - basic and diluted	41,016,075	31,380,634	40,095,945	31,723,792

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

For The Three Months Ended September 30, 2023
(Unaudited)

	Preferred Shares		Common Shares		Common Shares Issuable		Additional Paid in Capital	Accumulated Deficit	Total
	Shares	Amount	Shares	Amount	Shares	Amount			
Balance, June 30, 2023	96	\$ 1	40,640	\$ 41	-	\$ -	\$ 688,408	\$ (676,687)	\$ 11,763
Fair value of vested stock options	-	-	-	-	-	-	433	-	433
Issuance of common stock to an officer and a board member for services	-	-	400	1	-	-	114	-	115
Issuance of common stock in settlement of accounts payable and accrued expenses	-	-	379	-	-	-	110	-	110
Net loss	-	-	-	-	-	-	-	(2,416)	(2,416)
Balance, September 30, 2023	96	\$ 1	41,419	\$ 42	-	\$ -	\$ 689,065	\$ (679,103)	\$ 10,005

For The Nine Months Ended September 30, 2023
(Unaudited)

	Preferred Shares		Common Shares		Common Shares Issuable		Additional Paid in Capital	Accumulated Deficit	Total
	Shares	Amount	Shares	Amount	Shares	Amount			
Balance, December 31, 2022	96	\$ 1	32,723	\$ 33	-	\$ -	\$ 686,168	\$ (674,468)	\$ 11,734
Private placement of common stock	-	-	3,600	4	-	-	6,264	-	6,268
Initial recognition of fair value of warrant liability	-	-	-	-	-	-	(5,831)	-	(5,831)
Fair value of vested stock options	-	-	-	-	-	-	1,337	-	1,337
Issuance of common stock to officer and board member for services	-	-	473	-	-	-	430	-	430
Issuance of common stock for exercise of Prefunded Warrants	-	-	2,900	3	-	-	(3)	-	-
Issuance of common stock in settlement of accounts payable and accrued expenses	-	-	1,723	2	-	-	700	-	702
Net loss	-	-	-	-	-	-	-	(4,635)	(4,635)
Balance, September 30, 2023	96	\$ 1	41,419	\$ 42	-	\$ -	\$ 689,065	\$ (679,103)	\$ 10,005

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

	Preferred Shares		Common Shares		Common Shares Issuable		Additional Paid in Capital	Accumulated Deficit	Total
	Shares	Amount	Shares	Amount	Shares	Amount			
Balance, June 30, 2022	96	\$ 1	30,694	\$ 31	-	\$ -	\$ 677,411	\$ (662,003)	\$ 15,440
Equity compensation to officers, employees, and board of directors	-	-	78	-	378	938	2,006	-	2,944
Issuance of common shares for services	-	-	135	-	-	-	1,200	-	1,200
Issuance of common shares in settlement of vendors payable	-	-	1,222	1	-	-	3,250	-	3,251
Net loss	-	-	-	-	-	-	-	(6,881)	(6,881)
Balance, September 30, 2022	96	\$ 1	32,129	\$ 32	378	\$ 938	\$ 683,867	\$ (668,884)	\$ 15,954

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

	Preferred Shares		Common Shares		Common Shares Issuable		Additional Paid in Capital	Accumulated Deficit	Total
	Shares	Amount	Shares	Amount	Shares	Amount			
Balance, December 31, 2021	96	\$ 1	32,062	\$ 32	327	\$ 1,113	\$ 674,348	\$ (653,584)	\$ 21,910
Cancellation of common stock upon settlement with former officer	-	-	(1,845)	(1)	-	-	(222)	-	(223)
Cancellation of common stock	-	-	(291)	-	-	-	-	-	-
Common shares issued upon conversion of notes payable	-	-	327		(327)	(1,113)	1,113	-	-
Equity compensation to officers, employees, and board of directors	-	-	242	-	378	938	2,916	-	3,854
Issuance of common shares for services	-	-	412	-	-	-	2,462	-	2,462
Issuance of common shares in settlement of vendors payable	-	-	1,222	1	-	-	3,250	-	3,251
Net loss	-	-	-	-	-	-	-	(15,300)	(15,300)
Balance, September 30, 2022	96	\$ 1	32,129	\$ 32	378	\$ 938	\$ 683,867	\$ (668,884)	\$ 15,954

GT BIOPHARMA, INC. AND SUBSIDIARIES
CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS
(in thousands)

	For The Nine Months Ended September 30,	
	2023	2022
	(Unaudited)	(Unaudited)
CASH FLOWS FROM OPERATING ACTIVITIES		
Net loss	\$ (4,635)	\$ (15,300)
Adjustments to reconcile net loss to net cash used in operating activities:		
Stock based compensation – common shares for services	430	5,713
Stock based compensation – vested stock options	1,337	3,854
Change in fair value of warrant liability	(4,796)	(81)
Gain on extinguishment of debt	(547)	-
Unrealized (gain) loss on marketable securities	(43)	53
Changes in operating assets and liabilities:		
Decrease in prepaid expenses	16	102
Increase in deposits	-	(9)
Decrease in operating lease right of use assets	78	70
Increase (decrease) in accounts payable and accrued expenses	1,437	(5,259)
(Decrease) in operating lease liability	(82)	(62)
Net Cash Used in Operating Activities	<u>(6,805)</u>	<u>(10,919)</u>
CASH FLOWS FROM INVESTING ACTIVITIES		
Sales (purchases) of investments	(2,487)	4,639
Net Cash Provided by (Used in) Investing Activities	<u>(2,487)</u>	<u>4,639</u>
CASH FLOWS FROM FINANCING ACTIVITIES		
Proceeds from issuance of common stock and prefunded warrants	6,268	-
Cancellation of common stock upon settlement with former officer	-	(223)
Net Cash (Used in) Provided by Financing Activities	<u>6,268</u>	<u>(223)</u>
Net Decrease in Cash	(3,024)	(6,503)
Cash at Beginning of Period	5,672	8,968
Cash at End of Period	<u>\$ 2,648</u>	<u>\$ 2,465</u>
SUPPLEMENTAL DISCLOSURES OF CASH FLOW INFORMATION:		
Cash paid during the year for:		
Interest	\$ -	\$ -
Income taxes paid	\$ -	\$ -
SUPPLEMENTAL DISCLOSURES OF NON-CASH INVESTING AND FINANCING ACTIVITIES		
Right-of-use assets exchanged for lease liabilities	\$ -	\$ 260
Initial recognition of fair value of warrant liability	\$ 5,831	\$ -
Fair value of common stock issued to settle accounts payable and accrued expenses	\$ 700	\$ -
Common stock issued upon conversion of notes payable and accrued interest	\$ -	\$ 1,113



Source: GT Biopharma, Inc.